AMERICAN NATIONAL STANDARDS INSTITUTE

Report of Mail-In Audit of
MedBiquitous
ANSI-Accredited Standards Developer
January 2009

CONFIDENTIAL

Note: This audit report and the information contained herein shall remain confidential and shall not be disclosed to any person other than the auditee, appropriate ANSI staff, the auditor, and, as appropriate, members of the reviewing bodies (i.e., the Executive Standards Council, the Board of Standards Review and the ANSI Appeals Board). The auditee may provide the audit information and reports received to whomever it deems appropriate.

1. Introduction

The authority for ANSI to audit ANSI-accredited standards developers is included in clause 4.1.3 of the *ANSI Essential Requirements: Due Process Requirements for American National Standards (ANSI Essential Requirements).* The purpose of an audit is to determine whether there is any evidence of non-compliance with the criteria for accreditation and to ascertain as far as possible if the procedures and practices of an ANSI-accredited standards developer continue to be consistent with the current *ANSI Essential Requirements*. When possible, in a separate report, the auditor will recommend changes to the operation of the auditee that are intended to increase efficiency or effectiveness.

The *ANSI Auditing Policy and Procedures* allow an auditee to provide all relevant standards material to ANSI via the mail or electronically under circumstances approved by the Director of the ANSI Standards Developer Audit Program. The audit will then be performed without an on-site review of the developer's standards related documentation. It was determined that MedBiquitous was eligible for a mail-in audit.

Leslie Block served as the auditor. A pre-audit telephone conference was held on December 4, 2008 with Valerie Smothers, Deputy Director, MedBiquitous; Jody Poet, Administrative Manager, MedBiquitous; Leslie Block, ANSI Auditor; and Jay Moskowitz, Director, ANSI Standards Developer Audit Program. This provided an opportunity for questions and answers from both parties.

2. Background

MedBiquitous ("MedBiq") has been an ANSI-accredited standards developer since March 17, 2004 and was reaccredited on April 30, 2008. According to their website, MedBiq "is a non-profit, international group of professional medical and healthcare associations, universities, commercial, and governmental organizations dedicated to advancing healthcare education through technology standards that promote professional competence, collaboration, and better patient care."

3. Scope of the Audit

The audit involved a review of the operations of MedBiq as related to standards development and associated activities, including continuity of administrative oversight

and support of the standards activities. As MedBiq has two American National Standards, based upon criteria administered by the Director of the ANSI Standards Developer Audit Program, the scope called for one standard to be selected for the audit.

This audit report, including the findings, is based solely on the standards and documentation actually reviewed. The audit report should not be viewed or relied upon as evidence of anything beyond the scope of the documentation reviewed. The audit did not involve the accounting or financial aspects of MedBiq.

The audit took into consideration the practices and actions, records and reports of MedBiq in implementing its operating procedures to comply with ANSI criteria, rules, procedures and requirements including, but not limited to, the following items:

- Criteria for Accreditation
- Due Process Requirements
- Criteria for Approval and Withdrawal of American National Standards
- Other ANSI Requirements

4. Audit Objectives

The following audit objectives formed the basis of the audit:

- Based on the evidence reviewed, confirm adherence by MedBiq to the criteria for accreditation.
- Based on the evidence reviewed, confirm that MedBiq procedures and practices continue to be consistent with approved procedures and with current ANSI requirements.
- Recommend changes in procedure when, in the opinion of the auditor, such changes would result in more efficient or effective operations.

5. Summary of Audit Results

The audit identified areas where activities are notable, as indicated in Section 8A of this report. Under separate cover, suggestions for potential improvements in efficiency and effectiveness are offered for consideration. The audit also identified several areas where the auditor believed certain findings and recommendations were appropriate, as indicated in Section 8B of this report.

6. Conduct of the Audit

After initial preparation, including the completion of the pre-audit checklist by MedBiq, the audit was conducted in three phases: an examination of records and documentation by the auditor; development of audit findings, recommendations and comments by the auditor; and a post-audit conference with MedBiq staff.

7. Examination of Records and Documents

MedBiq provided the auditor with a copy of the completed pre-audit questionnaire (Attachment A), as well as documentation substantiating the responses. A review of the pre-audit questionnaire and the accompanying documentation provided the following general findings:

MedBiq, as an ANSI-Accredited Standards Developer, has unique accredited procedures, the MedBiquitous Standards Program Operating Procedures ("MedBiq's Procedures"). (Attachment B) The standards development process is as follows:

A MedBiq member organization submits a proposal for a new standard on the MedBiquitous Standards Recommendation form. The Executive Committee evaluates the proposal and decides whether to take on the project as an ANS. If they decide to do so, the Executive Committee submits a PINS form to ANSI. The Executive Director assigns the standards development project to the Standards Committee and the appropriate Working Group. The Working Group prepares the draft standard and presents it to the Standards Committee, which is the consensus body, for comment. The Standards Committee reviews the draft standard and provides comments to the Working Group, which revises the draft standard if necessary. The Standards Committee presents the draft standard to the Executive Director, who then submits the BSR-8 to initiate public review. The Working Group reviews any comments received via public review and incorporates any changes if necessary. The Standards Committee then evaluates the official draft standard and either approves or sends it back to the Working Group for additional changes until conflict is resolved.

The auditor noted that MedBiq's procedures do not include language to address receipt of comments not related to the proposal under consideration.

MedBiq sponsors two ANSI-approved standards. The organization staff responsible for the maintenance of MedBiq's American National Standards is Valerie Smothers, Deputy Director, and Jody Poet, Administrative Manager.

Internationally, there is no parallel or related standards program.

Nationally, MedBiq has an Associates Agreement/Memorandum of Understanding with HL7.

The staff of MedBiq do not participate on the ANSI Organization Member Forum. The staff of MedBiq participate on ANSI's Health Care Information Technology Standards Panel ("HITSP").

Jody Poet, Administrative Manager has attended ANSI's American Way training course and provides access to training documents received as well as guidance to other MedBiq staff.

MedBiq extensively uses electronic media to provide information to volunteers and the public at large. All MedBiq Standards Committee work is conducted electronically, by use of a Wiki site, which also includes minutes of meetings and relevant documentation. MedBiq files ANSI forms electronically via email attachment or web form.

MedBiq has a Standards Interpretation Policy, which is contained in Section 17.0 of MedBiq's Procedures and is on file at ANSI. The policy does not require that requests or responses be provided in writing and does not detail the process by which responses are developed. No interpretations of MedBiq's standards have been requested.

MedBiq has a Records Retention Policy, which is contained in Section 14.0 of MedBiq's Procedures and is on file at ANSI. The policy states that "[r]ecords that provide documentation or history of the standards program shall be kept permanently." However, the Section 14.2 of the policy also includes a provision for records to be kept for three years; those records should be kept for one complete standards cycle, or until the standard is revised, in accordance with clause 3.3.1 of the *ANSI Essential Requirements*. The auditor noted that MedBiq appears to be in compliance with its policy, and it retains records electronically. However, the policy needs to be revised to comply with ANSI's requirements.

MedBiq has a Metric Policy, which is contained in Section 18.0 of MedBiq's Procedures and is on file at ANSI. The policy requires that that "[i]n order to maintain consistency between various ANSI/Medbiquitous Specifications, all Medbiquitous Specifications [should] include SI units . . . ." The auditor noted that upon reviewing the standard, it does not appear to be measurement-sensitive.

MedBiq has a Commercial Terms and Conditions Policy, which is contained in Section 21.0 of MedBiq's Procedures. The auditor noted that the Commercial Terms and Conditions Policy appears to comply with the *ANSI Essential Requirements*.

MedBiq has a Patent Policy, which is contained in Section 19.0 of MedBiq's Procedures and is on file at ANSI. MedBiq uses a compliance statement as its Patent Policy, which complies with the ANSI Patent Policy. No patent issues have been reported.

The auditor reviewed the questionnaire completed by MedBiq (Attachment A), as well as documentation substantiating the responses.

The auditor emphasized the following specific areas in the examination of MedBiq documentation:

A. Review of Documentation Indicating Evidence of Consensus and Due Process.

The auditor reviewed ANSI/MEDBIQ PP.10.1-2008, Healthcare Professional Profile.

- **PINS (Project Notification System)**

The auditor noted that MedBiq submitted a properly-completed PINS form for PP.10.1-2008 on July 19, 2005 (Attachment C). The auditor noted that the form was submitted as an attachment to email. The auditor noted that the submission of the PINS form was not timely, as the MedBiq Executive Meeting minutes of June 1, 2005 indicate the initiation of the ANSI standards development project at that time (Attachment D).

- **BSR-8 (Standards Action Public Review Request Form)**

The auditor noted that MedBiq submitted its first BSR-8 on January 30, 2007. This form was submitted via web form and was completed correctly. This BSR-8 form was submitted before the balloting of the standard, which was initiated on December 2007. The auditor noted that the second BSR-8 form was submitted on April 14, 2008. This form was submitted after the initiation of the recirculation ballot, which occurred on March 14, 2008. This form was submitted via web form and was completed correctly. The auditor noted that the first public review was conduced prior to the first ballot, and the second public review was conducted after the recirculation ballot.

- **BSR-9 (ANS Formal Submittal Checklist)**

The auditor noted that MedBiq submitted a BSR-9 form on June 12, 2008 as an attachment to email. MedBiq included a complete consensus body list including interest categories. This form was submitted within one year of the close of public review. The auditor noted that the tally reported on the BSR-9 agreed with the ballots and final tally sheet.

B. Review of Documentation Indicating the Disposition of Views and Objections

This section covers comments received from the consensus body and public review and how those comments were addressed in accordance with the *ANSI Essential Requirements.*

The auditor noted that MedBiq conducts its balloting using the web and that the consensus body is the Standards Committee. The auditor noted that Section 8.1.4 of MedBiq's Procedures requires a ballot length of six weeks (or less if all ballots are returned). The auditor noted that the first ballot was initially open from December 4, 2007 through January 16, 2008, which is 44 days. Ballot reminders were sent on January 2, 2008 and January 15, in compliance with Section 8.1.4 of MedBiq's Procedures. On January 24, the ballot was extended due to the fact that nine organizations were inadvertently omitted from the initial ballot. The ballot was extended until February 15, 2008, and another reminder was sent on February 4, 2008. The auditor noted that this extension only provided those nine organizations with a ballot duration of 23 days, less than the six weeks required by MedBiq's Procedures.

The auditor noted that due to substantive changes in the draft standard, MedBiq issued a recirculation ballot on March 14, 2008 with a closing date of April 14, 2008, which is a period of 32 days, in compliance with Section 8.6 of MedBiq's Procedures. This ballot was conducted via the web. The auditor noted that the email informing the Standards Committee of the recirculation ballot stated: "For those of you that voted in the . . . Professional Profile, you have the opportunity to change your vote based upon the changes made to the specifications as a result of the comments received. If you agree with the changes made and your vote was Affirmative or Affirmative with Comment, NO ACTION IS REQUIRED." (Attachment E) The auditor noted that from this phrasing, it does not appear that the committee members who did not vote on the initial ballot had the opportunity to vote as required by clause 2.6 of the *ANSI Essential Requirements*. The

auditor further noted that no consensus body member changed their vote during the recirculation ballot.

The auditor noted that one public review comment was received for ANSI/MEDBIQ PP.10.1-2008, from Paul Jolly of the Association of American Medical Colleges ("AAMC") on March 14, 2007. This comment included several proposed changes to the draft standard. MedBiq provided disposition of the comments in spreadsheet attached to an email dated August 15, 2007. Substantive changes were made to the draft standard based upon Jolly's comments. The auditor noted MedBiq staff states that at the time, Jolly verbally agreed that his objection was resolved; however, the auditor notes that this resolution was not done in writing, either with a written response back from Jolly or written correspondence from MedBiq to Jolly stating, for example, "we will consider this objection resolved if we do not hear from you in [a specified number of] days." The auditor noted that during the course of the audit, MedBiq contacted Jolly, and he provided MedBiq with written confirmation that his objection was resolved. (Attachment F)

The auditor noted that no negative votes were received during the balloting of the standard. The auditor noted that two "Affirmative with Comment" votes were received and responded to by MedBiq. One of those "Affirmative with Comment" votes was from Chris Candler of AAMC. Both suggestions were incorporated into the draft standard, and AAMC was informed of that in an email dated March 14, 2008. The second "Affirmative with Comment" vote was from Dan Rehak, an individual member of the consensus body. The auditor noted that that an email dated March 14, 2008 had an attached spreadsheet with the disposition of the comments. The email also stated the existence of the appeals process and a link to MedBiq's procedures, which contain the MedBiq Appeals Policy. The auditor noted that as a result of the resolution of these comments, substantive changes were made to the draft standard, and a second ballot and ANSI public review were conducted.

The auditor noted that the MedBiq Working Group reviews any comments and responds to them in writing in accordance with Section 8.6 of MedBiq's Procedures.

The auditor noted that, as explained above, there were no unresolved objections to the draft standard. The apparent unresolved objection from the public review commenter Paul Jolly was resolved as explained above.

The auditor noted that when substantive changes were made to the draft standard, the consensus body had the opportunity to review those changes and a recirculation ballot was conducted. The auditor further noted that an additional public review was conducted.

C. Balance and Interest Categories of Consensus Body

The auditor noted that MedBiq has no limits on the size of the consensus body. The auditor noted that there is no fee for participation on the consensus body for members of

the MedBiq Consortium; non-members must pay a $200 fee to participate. The auditor noted that MedBiq has a fee waiver.

The auditor noted that no members of the consensus body were suspended for non-participation.

The auditor noted that MedBiq utilizes its website to advise interested and affected persons of MedBiq's standards activities and to invite participation.

The auditor noted that the consensus body list is maintained by MedBiq staff and is posted on the MedBiq website.

The auditor noted no evidence of dominance.

The auditor noted that the consensus body does not appear to be balanced. Evidence of outreach was included with the submission of the BSR-9 (Attachment G). Outreach conducted by MedBiq includes:

- Exhibiting and participating in healthcare education industry meetings to promote MedBiq activities and encourage broad participation in the Standards Committee by Professional Medical Societies, Universities, Specialty Boards, State Licensing Boards, E-learning Providers, Learning Management Software Companies, Pharmaceutical and Device Companies, and Publishers, and Government;
- Special effort to reach out to software companies serving the education industry by visiting their exhibit booths at conferences;
- Asking members in the User category to refer MedBiq to their partners in the technology development, publishing, and pharmaceutical and device. (According to MedBiq, these referrals have resulted in several new members of the Standards Committee.);
- Holding an Annual Conference to bring together MedBiq's standards development community. (Producers and users are encouraged to attend and participate in working group meetings. Plenary sessions call attention to the open nature of the Standards Committee and encourage attendees to participate.); and

- Making the Standards Committee application available online.

The auditor noted that the balance of interest categories used for ANSI/MEDBIQ PP.10.1-2008, was as follows:

IntCateg	Affirm	Neg	Abst	Ballot NR	Total
User	12	0	0	14	26 (70.2%)
Producer	7	0	0	2	9
General Interest	2	0	0	2	2
Total	21 (56.8%)	0	0	16	37

1. The consensus body appears not to be balanced in accordance with MedBiq's Procedures, with the largest interest category at 70.2% of the total. (As a non-safety standard, no single interest category may be greater than a majority.)
2. Numerical approval requirements appear to have been met, with approval by 56.8% of the total membership (a majority of the total membership is required), and by 100% of those voting (two-thirds of those voting, excluding abstentions, is required).
3. Participation included 56.8% of the total membership.
4. The auditor found no evidence of dominance.

D. Appeals

The auditor noted that MedBiq has received no appeals for ANSI/MEDBIQ PP.10.1-2008.

The auditor noted that MedBiq's appeals policy is found in Section 12.0 of MedBiq's procedures. The auditor noted that Section 12.7 of the policy addresses further appeal to ANSI; this section should be deleted.

The auditor noted that the appeals policy appears to meet ANSI requirements other than the recommended revision to the policy mentioned above.

The auditor noted that Section 8.6 of MedBiq's Procedures states that unresolved objectors "shall be informed that an appeals process exists within procedures used by the standards developer," but does not specify that that notification shall be in writing. The auditor noted that this language needs to be added to MedBiq's Procedures.

E. Compliance with ANSI Requirements for Publication and Maintenance of Standards

In reviewing the MedBiq compliance with ANSI requirements for publication of standards, the auditor notes that MedBiq arranges for publication of their American National Standards. The American National Standard audited includes on the cover the words "an American National Standard" and the approved ANSI Logo. The date of publication is included on the title page. A unique alphanumeric designation is used to identify the American National Standards.

The auditor noted that MedBiq utilizes its website to announce the availability of MedBiq's standards.

In reviewing MedBiq's compliance with ANSI requirements for maintenance of standards, the auditor noted that no standards are out of compliance with the five-year review requirement.

8. Development of Audit Findings, Recommendations and Comments:

The auditor developed the following findings, recommendations and comments:

A. The auditor noted the following:

i) The auditor noted that MedBiq announces standards development activities extensively on its website. This encourages active participation in the development of MedBiq standards.

ii) The auditor noted that MedBiq utilizes the World Wide Web to announce information for those who are interested and have access to the web. The auditor believes that use of the World Wide Web increases the visibility of the standards and potentially increases participation on the consensus body.

iii) The auditor noted that MedBiq makes a substantial effort to resolve all comments and objections and to ensure that consensus is achieved. In reviewing the actions taken, the auditor found that the consensus body was willing to make substantive technical changes, even though the time for approval of the standard was lengthened.

iv) The auditor noted that MedBiq procedures define consensus as "approval by at least a majority of the Standards Committee membership and at least two-thirds of those voting, excluding abstentions."

v) The auditor noted that MedBiq has a $200 fee for participation on the consensus body (for non-Consortium members); however, in the opinion of the auditor the fee is reasonable and does not limit membership. The auditor further noted that MedBiq has a fee waiver policy. The auditor noted that no fee waivers have been requested.

vi) The auditor noted that membership on the consensus body is not restricted on the basis of technical qualifications. Participation is not conditional upon membership in any organization.

vii) The auditor noted that the interest category of participants is subject to approval by a majority vote of the Standards Committee after the participant's application has been processed.

viii) The auditor noted that MedBiq submits ANSI PSA forms electronically, thus reducing the potential for delays and errors.

ix) The auditor noted that no appeals of the approval of the MedBiq standards have been filed. The appeals process is outlined in Section 12.0 of MedBiq's Procedures.

x) The auditor noted that MedBiq has an Associates Agreement/Memorandum of Understanding with HL7.

xi) The auditor noted that MedBiq is not aware of any related international activity in the area of standardization.

xii) The auditor noted that MedBiq's American National Standards are available on MedBiq's website, www.medbiq.org.

xiii) The auditor noted that MedBiq is using the ANSI Patent Policy found in clause 3.1 of the *ANSI Essential Requirements* as the MedBiq patent policy.

xiv) The auditor noted that MedBiq has a Commercial Terms and Conditions Policy, contained in Section 21.0 of MedBiq's Procedures.

xv) The auditor noted that the completed MedBiq 2009 Compliance Form is on file with ANSI.

xvi) The auditor noted that MedBiq has a Standards Interpretation Policy, which is contained in Section 17.0 of MedBiq's Procedures and is on file at ANSI. The policy does not detail how a response to an interpretation request is developed. The auditor noted that no interpretations have been requested.

xvii) The auditor noted that MedBiq has representation on the ANSI Health Care Information Technology Standards Panel ("HITSP").

xviii) The auditor noted that MedBiq's files are in good order and were easy to follow, with a minimum number of miss-files or errors. This allowed the auditor to complete the audit quickly with a minimum of delays.

xix) The auditor noted that MedBiq's Procedures contain a clear and useful flow chart describing the standards development process.

xx) The auditor noted that MedBiq has a Metric Policy, which is contained in Section 18.0 of MedBiq's Procedures and is on file at ANSI. In brief, the policy requires that that MedBiq's standards should include SI units.

B. The auditor found areas of non-compliance and procedural concern. The following recommendations are made to address these non-compliances:

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.

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.

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.

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.

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.

vi) The auditor recommends that the non-compliances listed in this audit report be reviewed at the next scheduled audit to verify that corrective action was taken.

9. Post Audit Conference

The findings, recommendations and comments were discussed during a post audit teleconference call that was held on April 17, 2009. Those who participated were Valerie Smothers, Deputy Director, MedBiquitous; Jody Poet, Administrative Manager, MedBiquitous; Leslie Block, ANSI auditor; and Mr. Jay Moskowitz, Director, ANSI Standards Developer Audit Program.

Finally, the auditor would like to express appreciation for the cooperation extended by the MedBiq staff, which helped significantly in expediting the audit process, enabled the audit to be effective, and provided an opportunity for discussions benefiting ANSI as well as MedBiq.