

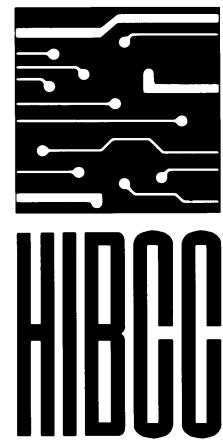
MINUTES

AUTO-ID TECHNICAL COMMITTEE MEETING

University of Memphis

Memphis

Thursday, June 12, 2014



Members Present:

Sprague Ackley, Intermec by Honeywell

Harry Manolopoulos, MiSim

Sheri Hudson, Northwestern Memorial Hospital

Kirk Kikirekov, HIBCC AU, Committee Chair

Members Absent:

In Mun, HCA

Others Present:

Scott Yakubek, Innovar Systems

Robert Hankin, HIBCC President

Farnoush Khamedoost, HIBCC

Call to Order

This meeting was called to order by the Chair, Kirk Kikirekov at 9:00 a.m.

Anti-Trust Policy and Conflict of Interest Statement

The Anti-Trust Policy and Conflict of Interest (COI) Statement were reviewed. Committee members read and acknowledged their obligations in relation to Anti-Trust and Conflict of Interest.

Approval of Agenda

The Chair, Kirk Kikirekov read out the agenda.

A motion was made by Chair, Kirk Kikirekov to approve the agenda. This was seconded by Harry Manolopoulos. The motion was carried.

Approval of Minutes

Sprague Ackley advised that minor corrections made to minutes. The official name of the company that Sprague Ackley works for is "Intermec by Honeywell". This correction to be made in the "Members Present" section, as well as the "Committee Roster" section.

Subject to this change, Harry Manolopoulos moved that the minutes be approved. The motion was seconded by Sheri Hudson. The motion was carried.

Committee Roster

The current committee roster was read by the Chair. The current roster being:

- Sprague Ackley, Honeywell Intermec
- Sheri Hudson, Northwestern Memorial Hospital
- Harry Manolopoulos, MiSim
- In Mun, HCA
- Kirk Kikirekov, HIBCC AU

A motion was made by Sheri Hudson to approve the committee roster, seconded by Harry Manolopoulos. The motion was carried.

Existing HIBCC Standards

The Chair advised that all standards bar the PIPS standard are current. Sheri Hudson advised that the PIPS standard should be re-opened to add a specification for the capture and recording of Human Bone and Tissue products.

The Chair moved that the standard be re-opened for the inclusion of this standard. Sheri Hudson seconded the motion. The motion was carried.

Sheri Hudson and Harry Manolopoulos will work on incorporating the Human Bone and Tissue Specification into the PIPS standard. When this work completed, the draft standard will be circulated to Committee for comment. It is intended that a draft of the standard be completed by the December meeting, at which time the Committee will vote to publish the standard for public comment with ANSI.

Stand Alone Software

The Committee discussed a coding convention for identifying the version of standalone software. It was agreed that the longstanding convention used for coding Versions of software could be accommodated in HIBCC SLS using the Lot number field. This would allow the use of the Period “.” In the coding of the software version and build. For example V4.20001.001.

Sprague Ackley will produce a guidance document for coding software version.

Contact Lenses – Convention for Coding

The Committee discussed the convention for coding gas permeable contact lenses. These products are manufactured as “blanks” by the material manufacturers. This includes companies such as Alcon and Bausch and Lomb. However, the finished lenses are made by labs that custom make for patients needing contact lenses. The committee engaged in a teleconference with a representative from the Contact Lens Manufacturers association to understand the requirements more specifically.

Following this teleconference, it was agreed as follows:

- Each individual lab would need to register with HIBCC as a labeler
- The straightforward application of the HIBCC standard would be required by the labs, whereby the model of the lens is encoded in the primary data string and the serial number encoded in the secondary data string.

NCPDP Issue

The Committee considered the letter from Teresa Strickland of the NCPDP in relation to coding of Prescription Drugs.

The Committee concluded that given that the HIBCC is a registered issuing agency of the FDA in relation to UDI, that any company subscribing to the HIBCC standard would be bound by the HIBCC SLS specification in relation to UDI. Therefore, there would be no further restrictions placed on subscribers of the HIBCC SLS.

The Committee agreed that Robert Hankin will write to the NCPDP with this advice from the Committee.

Levels of packaging guideline

The Committee discussed the various scenarios pertaining to levels of packaging, including where it may not be practical to include a UDI to certain products, for example individual screws and plates.

It was of the view by Sprague Ackley that the UDI will only be required to be placed on the levels of packaging where manufacturers are currently applying labels. Therefore, it is to the smallest saleable unit.

It was agreed by the Committee that further advice and interpretation of the UDI rule is required before any definitive advice can be provided in relation to this issue.

Guidelines for exceptions to using Standard UDI

The Committee discussed the Sirtex Medical situation where they had been using the ANSI MH10 Data identifiers in a Datamatrix. It was agreed by the Committee that some manufacturers may have special requirements, and that the use of ANSI MH10 as permitted under the HIBCC standard should be an acceptable option for companies that have special needs.

Other Business

The Chair invited committee members to table any other business. No other business was tabled by the committee.

Adjourn

The meeting was adjourned by the Chair at 15:15 PM.