

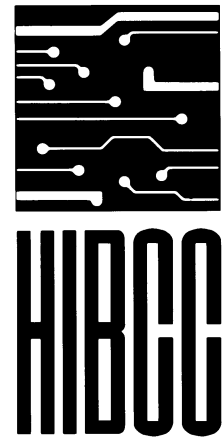
## MINUTES

### **AUTO-ID TECHNICAL COMMITTEE MEETING**

Pointe Hilton

Phoenix, AZ

Thursday, December 11, 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

#### **Guests Present:**

Robert Hankin, HIBCC President

Allison Mehr, HIBCC

Paul Pulley, Code Corp

Patrick DeGrace

Duwayne Schlitten, St Alexius Hospital

#### **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. Due to Honeywell Policy, it is noted that Sprague Ackley is unable to sign the Conflict of Interest Statement.

#### **Approval of Agenda**

The Chair, Kirk Kikirekov read out the agenda. The Chair added to the agenda the item for Paul Pulley of Codecorp to brief the AITC on his company and interest in HIBCC and the AITC.

A motion was made by Harry Manopolous to approve the agenda. This was seconded by Sheri Hudson. The motion was carried.

#### **Approval of Minutes**

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

Given that In Mun has now been absent from 2 consecutive meetings, he will be removed from the Roster.

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

### **Paul Pulley, Codecorp**

Paul Pulley briefed the AITC on Codecorp and his general interest in the activities of HIBCC and the AITC.

### **Revision of PIPS Standard**

The Committee discussed the proposed addition of Implants and Tissues to the existing PIPS Standard (ANSI-HIBC 3.1).

Following much discussion, it was agreed that it would be preferable to draft a new Standard to address Human Tissue products.

Due to the potential for this addition to conflict with other standards, including the SLS (ANSI-HIBC 2.4) and also with the International Council for Commonality in Blood Banking Automation (ICCBBA) standards and initiatives, it was agreed to:

- a) Draft a new Standard (ANSI-HIBC 6.0) for Human Tissue Products
- b) Bob Hankin would arrange a discussion with executives from ICCBBA to brief them on the proposed new standard, and the intended audience and application of this standard
- c) Remove any reference to "Implants" from the standard, so that this does not conflict with other standards, including the FDA UDI initiatives.

### **Supplier Labeling Standard**

The meeting discussed the inclusion of the hyphen "-" and the period "." in the PCN component of the primary barcode. Following much discussion and the issue for backward compatibility, it was agreed to not allow this change. Harry Monolopoulos moved that this change be rejected. This was seconded by Sprague, and the motion carried.

The meeting also discussed how best to clarify the Human Readable string below the barcode, and to distinguish this from the other Human Readable data on product labels as required by the FDA regulations.

It was agreed that a front page should be added to the SLS standard providing this clarification, and any other clarification that may be necessary for the better understanding of practical issues pertaining to the SLS and its application.

A discussion about the format of the date was also discussed by the meeting. It was agreed that for companies that wish to use the YYYYMMDD format, they could instead use the supplemental data option for the expiration date, using the 14D Data Identifier (DI).

For the purpose of defining this specific option in the Supplier Labeling Standard, It was agreed to re-open the SLS standard. Committee ballots were filled out with the decision to take the re-opening of the SLS standard to the board, after which a BCR with ANSI would be filed.

### **Revision of RFID Standard**

The Chair, Kirk Kikirekov, advised the meeting that the RFID standard (ANSI-HIBC 4.0) is well out of date, and requires a significant revision.

It was agreed by the members of the AITC to open the Standard for review, and to form a subcommittee consisting of Sprague Ackley, Harold Oehlmann and Kirk Kikirekov to meet by teleconference in February 2015 to discuss the revision, and the work plan.

### **Promotion of PAS (ANSI-HIBC 1.3)**

The meeting discussed how best to promote the PAS. Following much discussion, it was agreed that the software Vendors such as Cerner and iSoft would have to be encouraged to incorporate the standard into their software applications.

The best forum for getting the message out is the HIMSS conference. Sprague Ackley will investigate how to get a speaking spot to discuss the PAS at the next HIMSS conference.

### **FDA Developments**

The Chair, Kirk Kikirekov, advised the meeting that there was much confusion regarding the FDA requirements on the format required for expiration and production dates, and for plain text information generally on product packaging and labels.

The Chair advised that this requirement for plain text information is not related to the Human Readable component of the barcode or UDI, but rather that the label contain in plain text clear information about the product's expiration and manufacture dates and other information, quite aside from the barcode and UDI.

It was agreed that the front page proposed earlier be used to clarify the FDA requirements for plain text.

### **Updated UDI and Barcode Generator on HIBCC website**

The Chair advised that the barcode and UDI generator is currently being revised, and that this would be deployed to the HIBCC website within the next few weeks.

### **Other Business**

The Chair invited committee members to table any other business.

The meeting discussed the possible dates and venue for the next AITC meeting in June. The week commencing 8<sup>th</sup> June was deemed to be the most suitable for all members. The venue is open at this stage, but it was suggested that the meeting be held in Newark.

### **Adjourn**

The meeting was adjourned by the Chair at 15:42 PM.