

Connectivity Industry Consortium
European Initiative Meeting 2005

Status Quo and Ongoing Work

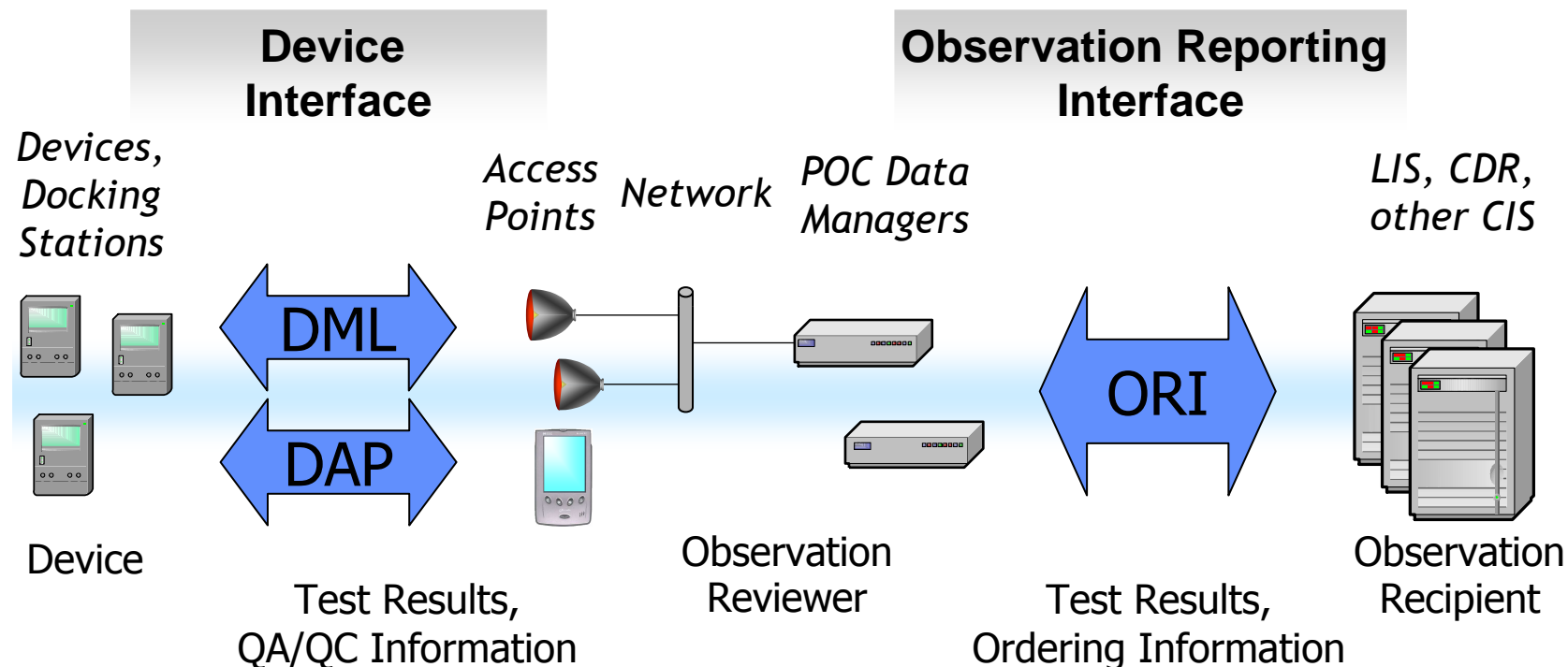
The process of adopting POCT1-A as a formal international standard

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NCCLS POCT1-A Standard

- developed 1999-2001 by POCCIC Industry Consortium using IEEE und HL7 components
- defines 2 Interfaces:
 - **Device Interface** (DAP: IEEE 1073, DML: HL7 V2.3 + XML)
 - **Observation Reporting Interface** (ORI: TCP / IP + HL7 V.2.3)



POCT1-A2 (March 2005) replaces POCT1-A

Parts:

- Main Document
- Appendix A. Device and Access Point (DAP) Interface Specification
- Appendix B. Device Messaging Layer (DML) Specification
- Appendix C. Observation Reporting Interface (ORI) Specification
- Appendix D. Point-of-Care Requirements
- Appendix E. Connectivity Architecture
- Appendix F. Vendor Codes

⇒ **enhanced accessibility and readability**

⇒ **moderate changes/extensions**

POCT1-A2 changes and extensions

■ Device Identifier: 3 Options

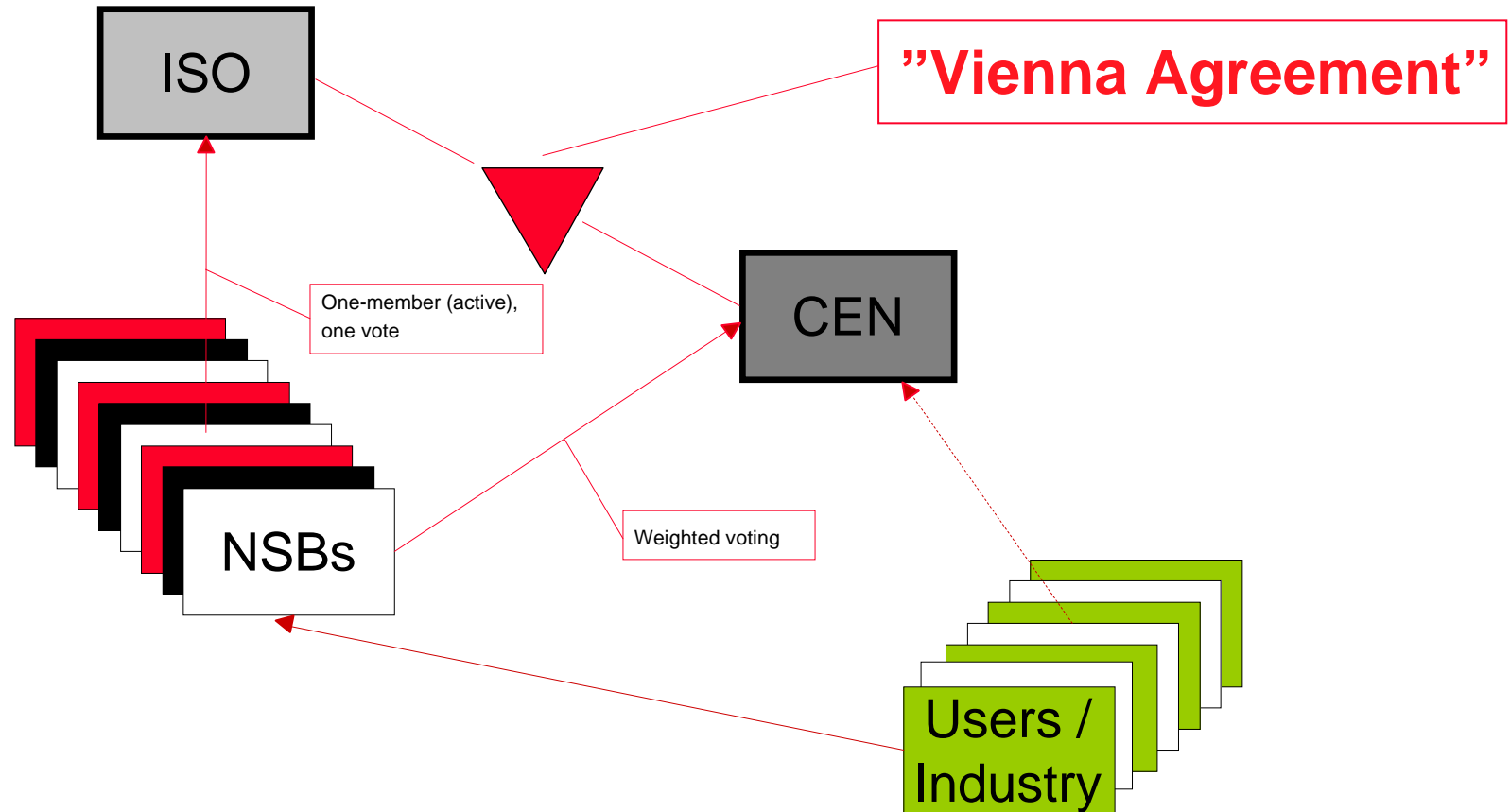
- EUI-64 (preferred)
- Concatenation of vendor_id, model_id, and serial_id fields from the device object of the DML using the ^ as a delimiter
- A legacy identifier string. distinguishable from EUI-64 and vendor_id

■ Naming of vendor-specific directive messages

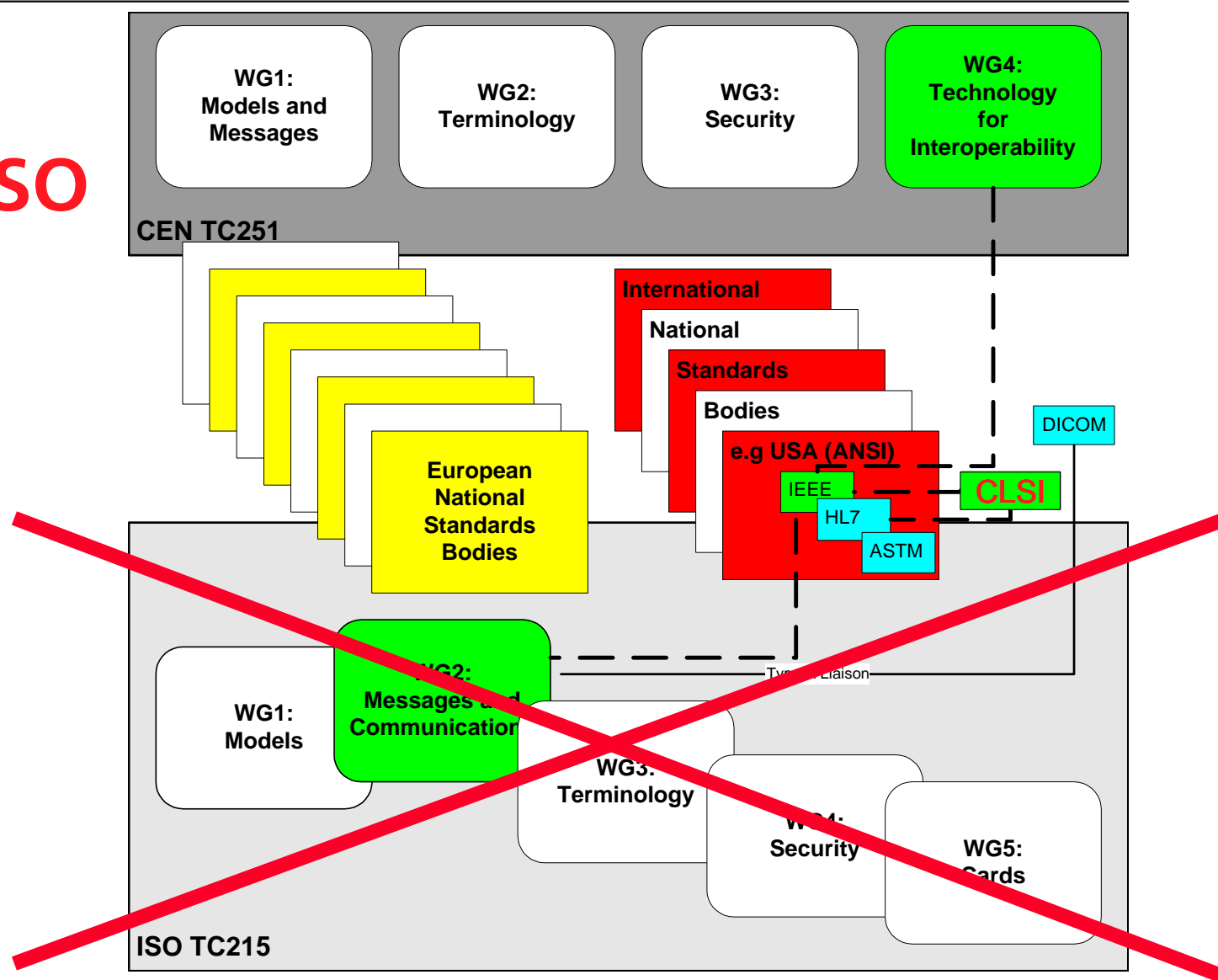
- Identification
- Use of Coded Vendor Identifier

■ Error corrections & minor textual improvements etc.

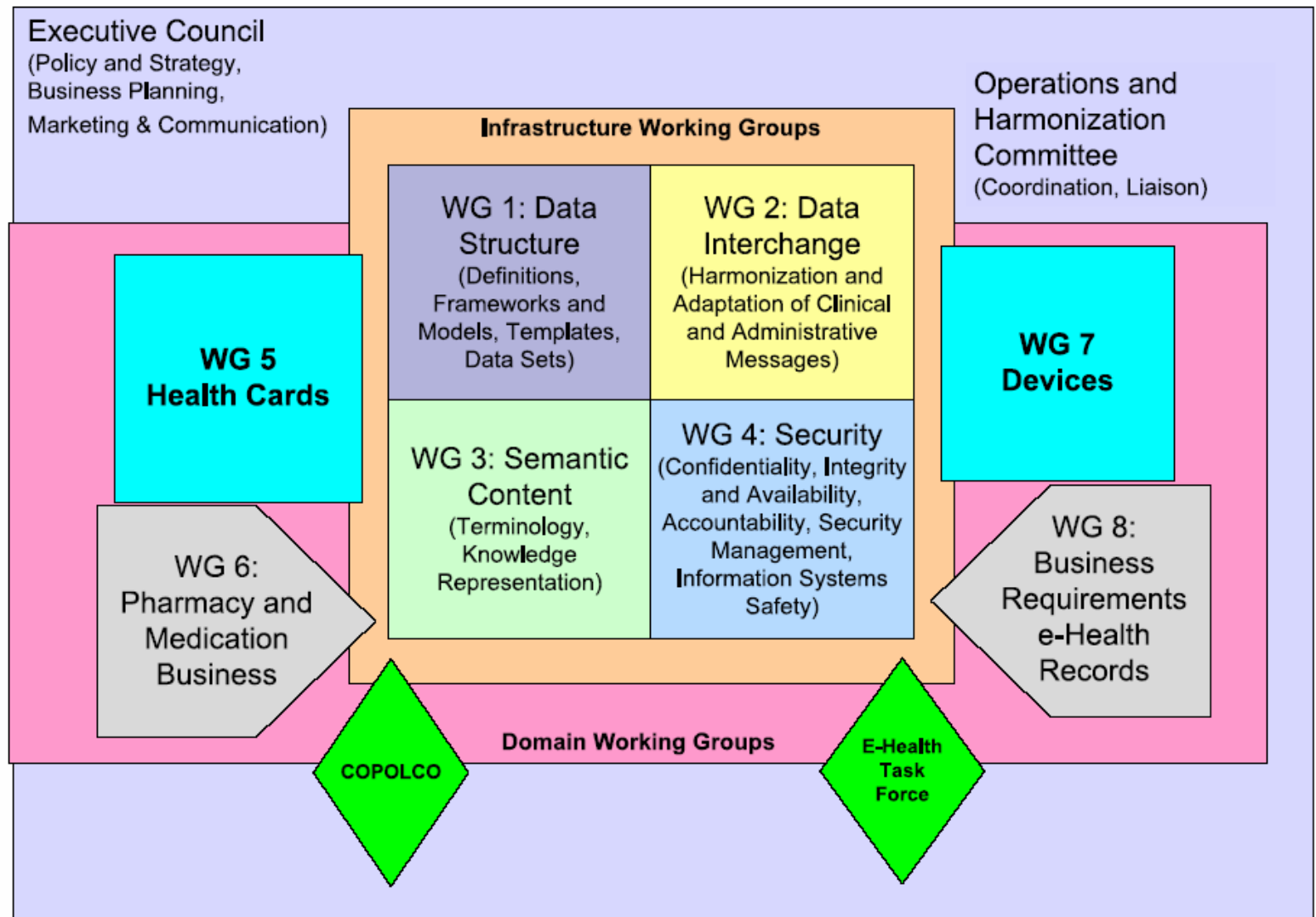
Joint CEN/ISO Work: How it works



CEN/IEEE/CLSI/ISO System of International Co-Operation



NEW ISO TC 215 Structure: WG7 "Devices"



Adoption of POCT1-A by CEN/ISO/IEEE

- "... Resolved that **ISO/TC 215** accepts the **POCCIC/NCCLS AUTO6-A** POCT standard "Health informatics – Analytical instruments – Point-of-care test" as a **fast track DIS ballot** with a designation of **11073-90100....**"
(Resolution 13 of ISO/TC 215: 30 August 2001, London / England)
- ⇒ **CLSI POCT1-A will be issued as ISO DIS11073-90100 as soon as copyright problems between ISO and CLSI (NCCLS) are solved**
- The **ISO/IEEE pilot process** ... (will) allow more countries to participate in the IEEE ballots than were permitted in either CEN or ISO. (...). At the ballot stage, parallel work items would be raised in ISO and CEN, with ISO to take the lead on the WI. There would also be parallel voting in the IEEE/ISO and CEN, with all comments raised to noted by the international experts and resolved. **This co-operative process (will) result in IEEE/ISO standards and CEN ENs...**
(Minutes of CEN/TC 251/WGIV Meeting October 2001, Stockholm / Sweden)
- ⇒ **Future ISO 11073-90100 will be issued in parallel as IEEE 1073 and CEN standard (thus overriding national standards in EU!)**

Adoption of POCT1-A by CEN/ISO/IEEE (2)

- Health informatics – Analytical instruments – Point-of-care test, **ISO 11073-90100**:
 - "... key problem that has been hindering the submission of the standard is the **lack of a copyright agreement between NCCLS and ISO**. ...(NCCLS and ISO) are working on resolving this problem as soon as possible..."
 - "... (ISO TC215 WG 2.1) has offered support to NCCLS in this regard (based on our experience with the IEEE and the HL7 pilot projects); ... (it) will also continue to follow-up on this effort, to ensure that it is progressing"

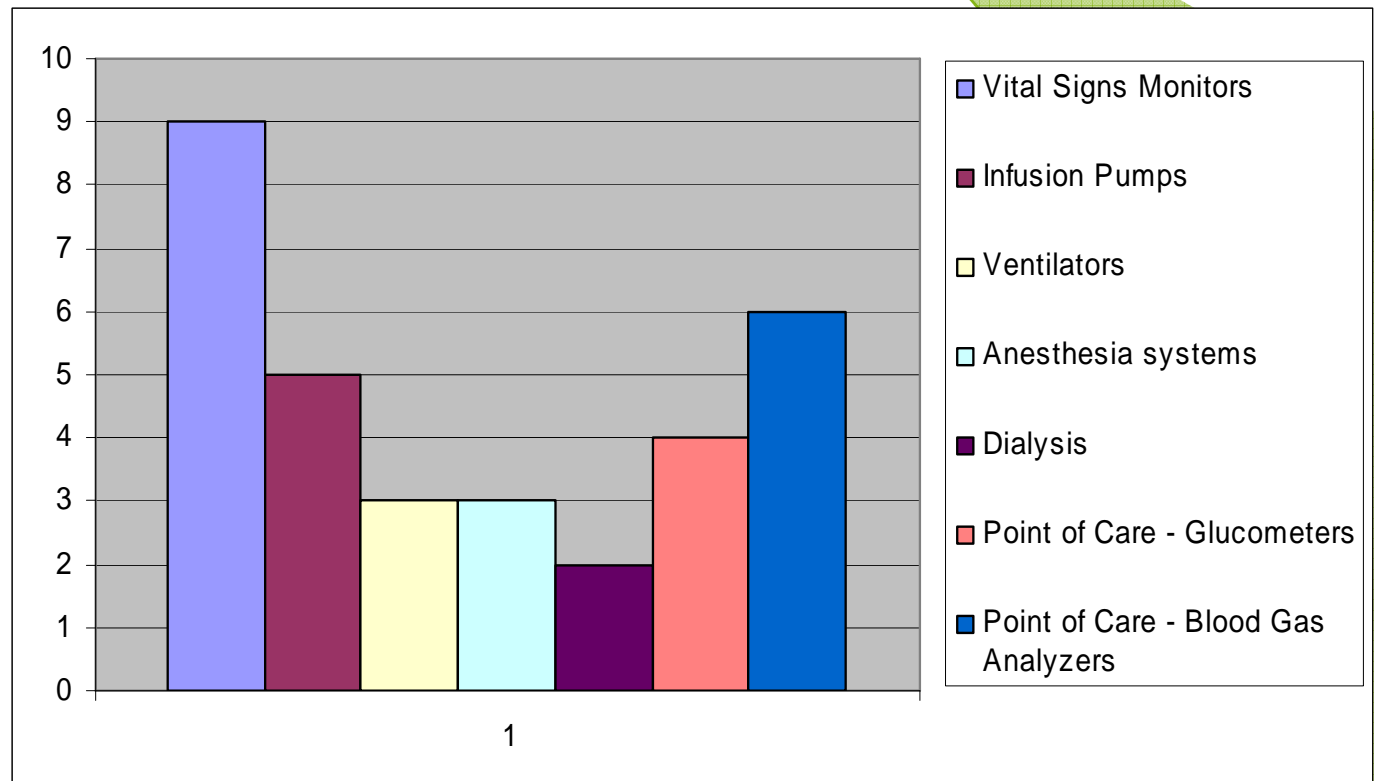
(Minutes of ISO/TC 215 Meeting August 2002, Melbourne / Australia) ■ ■ ■

- It was noted that the **NCCLS had become the CLSI** (Clinical & Laboratory Standards Institute) in January 2005 and that **this body would be submitting the POCT1-A standard draft to ISO/TC 215 for NWIP ballot** in the near future. All major proposed changes would be incorporated into the next draft. However, whilst the New WI Proposal should pass the ISO/TC 215 ballot, the accompanying draft should, nevertheless, not be approved on technical grounds.

(Minutes of 24th CEN/TC 251/WGIV meeting & ISO/TC 215 WG7 inaugural meeting jointly with IEEE 1073, May 2005, Berlin / Germany)

HIMSS Survey 2005: *How important is it for each device listed to become integrated under the IHE?*

- Highest priority devices are Vital Signs Monitors, Blood Gas Analyzers (POC), and Infusion Pumps



IHE Process

- Users and vendors work together to identify and design solutions for integration problems
- Intensive process with annual cycles:
 1. **Identify** key healthcare workflows and **integration problems**
 2. Research & **select standards** to specify a solution
 3. Write, review and **publish IHE Technical Framework**
 4. Perform **cross-testing** at “Connectathon”
 5. Demonstrations at tradeshow (HIMSS/RSNA...)

Organization of Technical Frameworks

● Volume 1: Integration Profiles

- Describes clinical need and use cases
- Identifies the actors and transactions

● Volume(s) 2(+):

- Provide implementation specification for transactions

Laboratory IHE Integration Profiles

Laboratory Scheduled Workflow (LSWF)

Completed in 2003

Tests performed by a laboratory for an identified inpatient or outpatient

Laboratory Point Of Care Testing (LPOCT)

In Process – TI Nov 2004

Tests performed on point of care or patient's bedside

Laboratory Patient Information Reconciliation (LPIR)

In Process

Tests performed on an unidentified or misidentified patient

Laboratory Code Set Distribution (LCSD)

In Process

Sharing the batteries and tests code sets throughout the enterprise

Laboratory Device Automation (LDA)

In Process – TI Nov 2004

Pre-analytic process, analysis and post-analytical treatment

IHE interested to leverage standards

- **2004-2005 IHE Lab for Point of Care Testing leverages NCCLS POCT1-A. Expects TC215 adoption.**
- **IHE Patient Care Devices (PCD) Domain Kick-off Meeting took place in Washington, 29-30 Sept. 2005.**
- **IHE-PCD Scope:** “The Patient Care Devices Domain is concerned with regulated patient care devices which do not fall within one of the other IHE clinical specialty based domains such as medical imaging.”

Thank you for your attention

Thomas Norgall

Chair CIC European Initiative

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