

# "Rationale for a Unique Device Identifier"

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**By using affordable commercial technology solutions combined with regulatory initiatives, we improve health provider's processes, increase patient safety and quality of care.**

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- **Why we need a UDI**

- Preventing **13,000-26,000 mortalities** in the US a year, from direct and indirect medical device procedure/ process infections
- **Saving \$3.1 Billion** a year from direct and indirect medical device procedure/ process infections
- Develop a comprehensive **interoperability healthcare model** to include medical non-electrical instruments and supplies

- **Factors to Consider for a UDI System**

- **UDI's Drivers**

- **The Impact of a Universal Device Identifier**

- **Concluding Remarks**

- **Ability to incorporate the UDI system into the Interoperability healthcare model**
- **Address unique life cycle events experienced by a medical device:**
  - **Reprocessing of medical devices and the associated regulations (FDC 502.u, SUD's)**
  - **Distributor re-labeling**
  - **Rentals**
  - **Loaners**
  - **Sterilization cycles**
  - **Maintenance cycles**
  - **FDA MDR/MHR and reporting**
  - **Adverse Event Reporting**
  - **State HAI Reporting**

- **Creating a De- Referenced Database environment where all authorized queries have Confidentiality, Integrity, Authentication and Anonymity”**
- **Patient privacy is controlled by the Patient so that they personally distribute and allow limited informational access by the inquiring party to their Patient health record.**
- **Focus on infection control: Designed a model to increase our abilities to better detect the chain of transmission infections, by integrating the UDI, procedure and patient record systems.**
- **Getting past the vested economic and political bias of the current players.**

- Device maintenance and increase regulatory compliance reporting, – in cases where infections have been passed from patient to patient due to improper device maintenance (Chain of Transmission )
- Reduce theft and counterfeiting of medical devices, Adverse Events warnings/notification
- Enable a process to track the reprocessing, recalls, rentals, loaning of medical devices and Reduce Counterfeit Instruments

- Increase supply chain asset visibility resulting in, increased productivity, administrative efficiencies, billing accuracy and reduction in Liabilities
- Matching patient data records to diagnosis, treatment and device to patient schedule/procedure and infection cause.
- Reduction of hospital associated infections and length of stay, reducing mortalities through ensuring sterilization and proper device usage on the correct patient.

# The Impact of a Universal Device Identifier

Issue	Solution	Result
<p><b>Lack of informatic tools and interoperability standards</b> to connect nomenclature to procedure, Patient records, Infection Control.</p> <p>What patients were treated with which devices?</p>	<p>Track process order events</p> <p><b>"The 7 Device L's":</b></p> <ol style="list-style-type: none"> <li>1. last manufacturer</li> <li>2. last maintenance</li> <li>3. last sterilization</li> <li>4. last location</li> <li>5. last user</li> <li>6. last procedure</li> <li>7. last patient.</li> </ol>	<p><b>13,000-26,000 mortalities</b> could be prevent in the US a year by developing a UDI pedigree model for medical tools in the healthcare Micro and Macro supply chain:</p> <p><b>Saving \$5 Billion a year</b></p>
<p><b>11 competing nomenclature systems</b> for the naming of medical devices</p>	<p>A <b>"Universal Translator"</b> (Nomenclature Sequencer Code)</p>	<p>Integrated global semantics into a unified interoperable relational standard</p>
<p><b>Lack of System</b></p> <p>"Confidentiality, Integrity and Authentication."</p>	<p>Privacy Preserving Index (PPI):</p> <p><b>Erroneous Data Generator and Filter</b></p>	<p>A secure relational database (NSS) that directs queries and information through the PPI</p> <p><b>creating a de-registered database environment for both Patient and Manufacturer</b></p>

# The Impact of a Universal Device Identifier

Issue	Solution	Result
<p><b>How to account</b> for maintenance, sterilization verification, reprocessing, loaning and rentals of Medical tools.</p>	<p>Placing additional data fields on an Auto-ID label</p>	<p>Third Party Liability Shift Labeling compliance Increased financial and compliance reporting efficiencies</p>
<p><b>Patient "Confidentiality, Integrity and Authentication."</b></p>	<p>Patient Controls release of personal information <b>Patient Record Confirmation Certificate</b></p>	<p>Several security check points culminating in the <b>patient issuing a one time access code to the inquiring party</b></p>
<p><b>Inconsistent reporting of Adverse events</b></p>	<p>A rules based <b>semi-automated mandatory</b> reporting system of adverse medical device related events</p>	<p><b>Combined reach</b> and techniques of MedSun and MAUDE <b>with the robust event reporting features</b> of ECRI Alerts Tracker. i.e. CDC-National Healthcare Safety Network</p>
<p>There are no plans to include Medical Instruments or Supplies In today's Global Healthcare Interoperability Models</p>	<p>UDI</p>	<p>A Complete Healthcare Interoperability model and all the gains realized: financial, efficiency, safety and quality</p>

- Failure to incorporate the comparative relationships (Medical Device- Universal Nomenclature- error reporting- patient record/ procedure- EHR) will yield an unstable interoperability healthcare model and will limit our ability to identify, analyze and eventually reduce medical errors and mortalities.
- **If we wait until UDI/Infection Control yields an immediate ROI or until we reach a global political compromise it may be too late.**
- **Don't wait for a catastrophic disease outbreak to implement UDI.**

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October 25, 2006

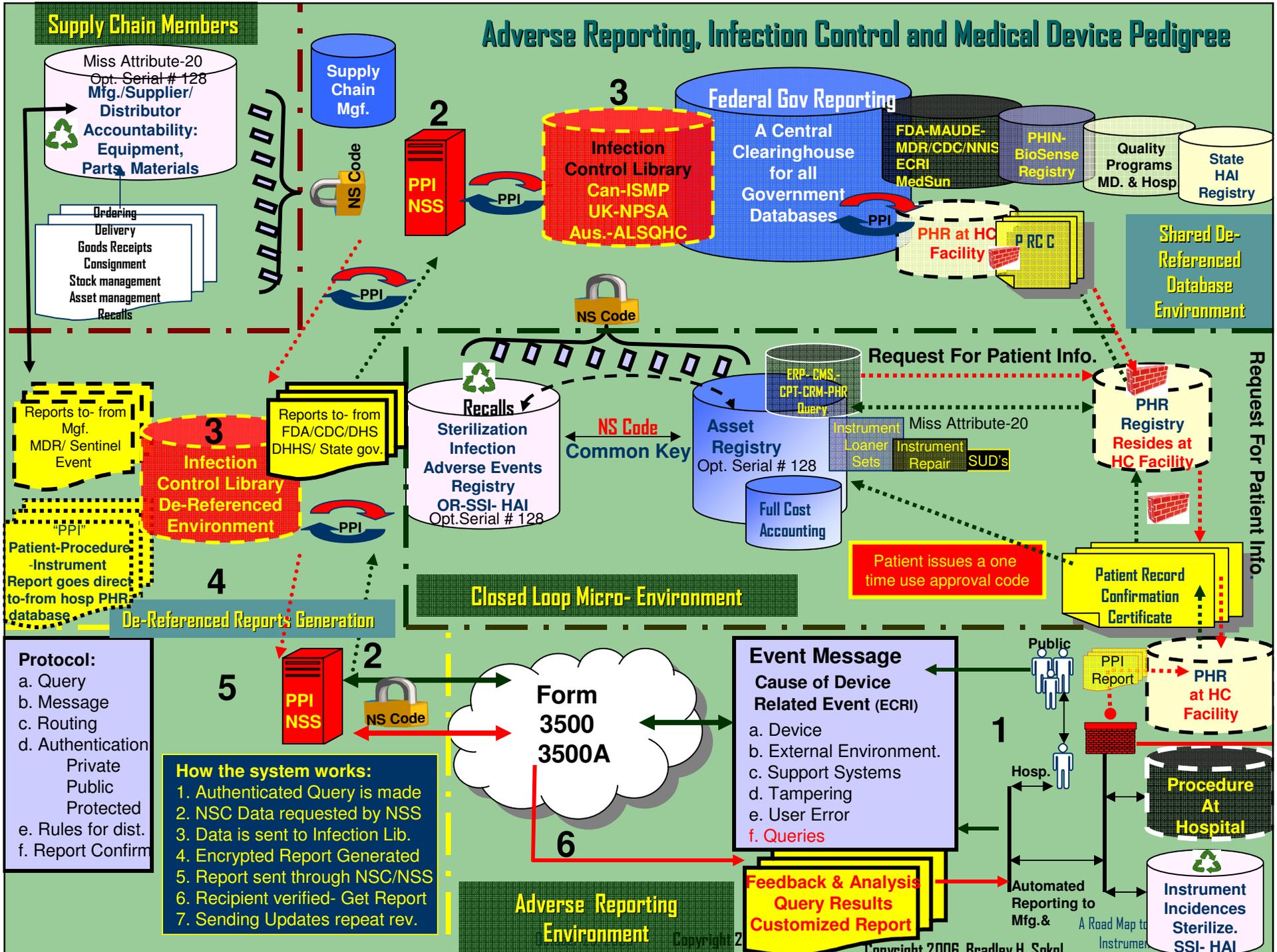
# Thank You!

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by healthcare tools" ©**

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A Road Map to  
Medical Device and Instrumentation Pedigree

# Adverse Reporting, Infection Control and Medical Device Pedigree



- Protocol:**
- Query
  - Message
  - Routing
  - Authentication
    - Private
    - Public
    - Protected
  - Rules for dist.
  - Report Confirm

- How the system works:**
1. Authenticated Query is made
  2. NSC Data requested by NSS
  3. Data is sent to Infection Lib.
  4. Encrypted Report Generated
  5. Report sent through NSC/NSS
  6. Recipient verified- Get Report
  7. Sending Updates repeat rev.

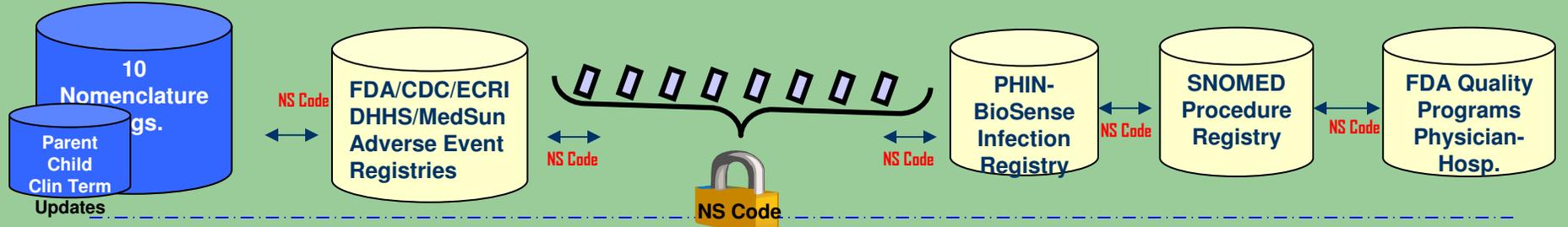
**Adverse Reporting Environment**

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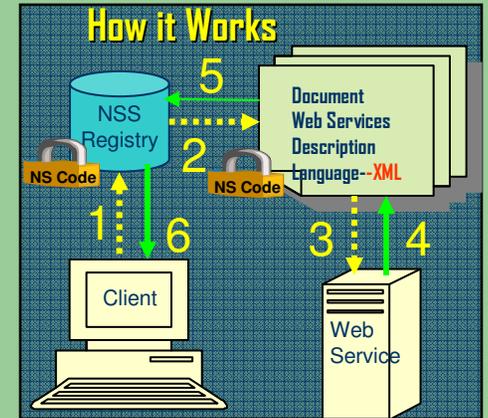
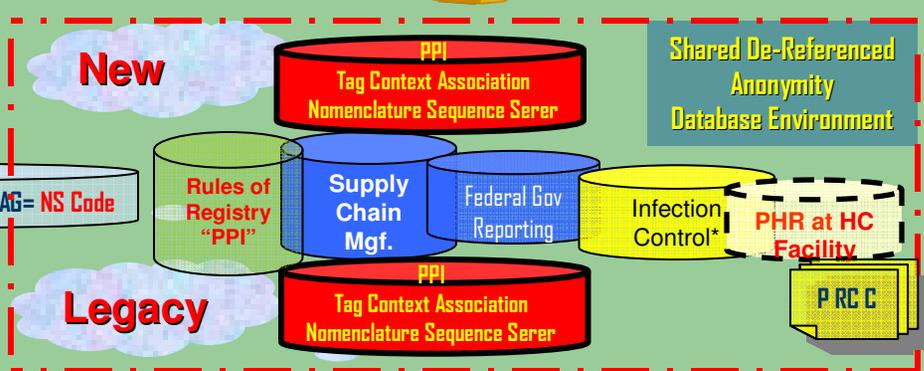
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A Road Map to Instrument

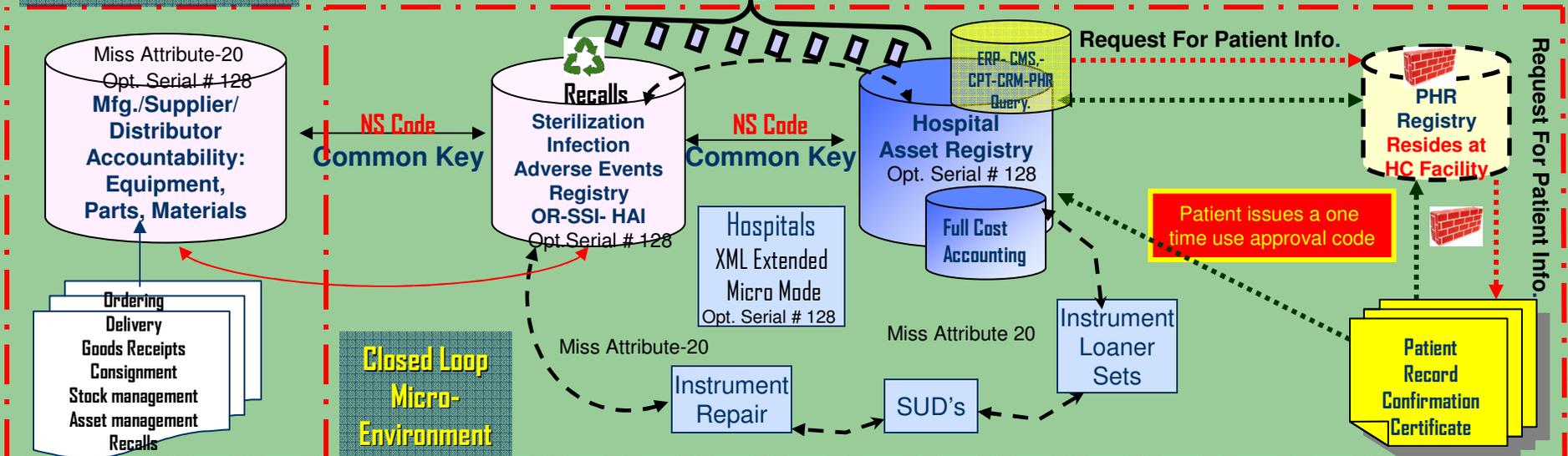
# Context Databases

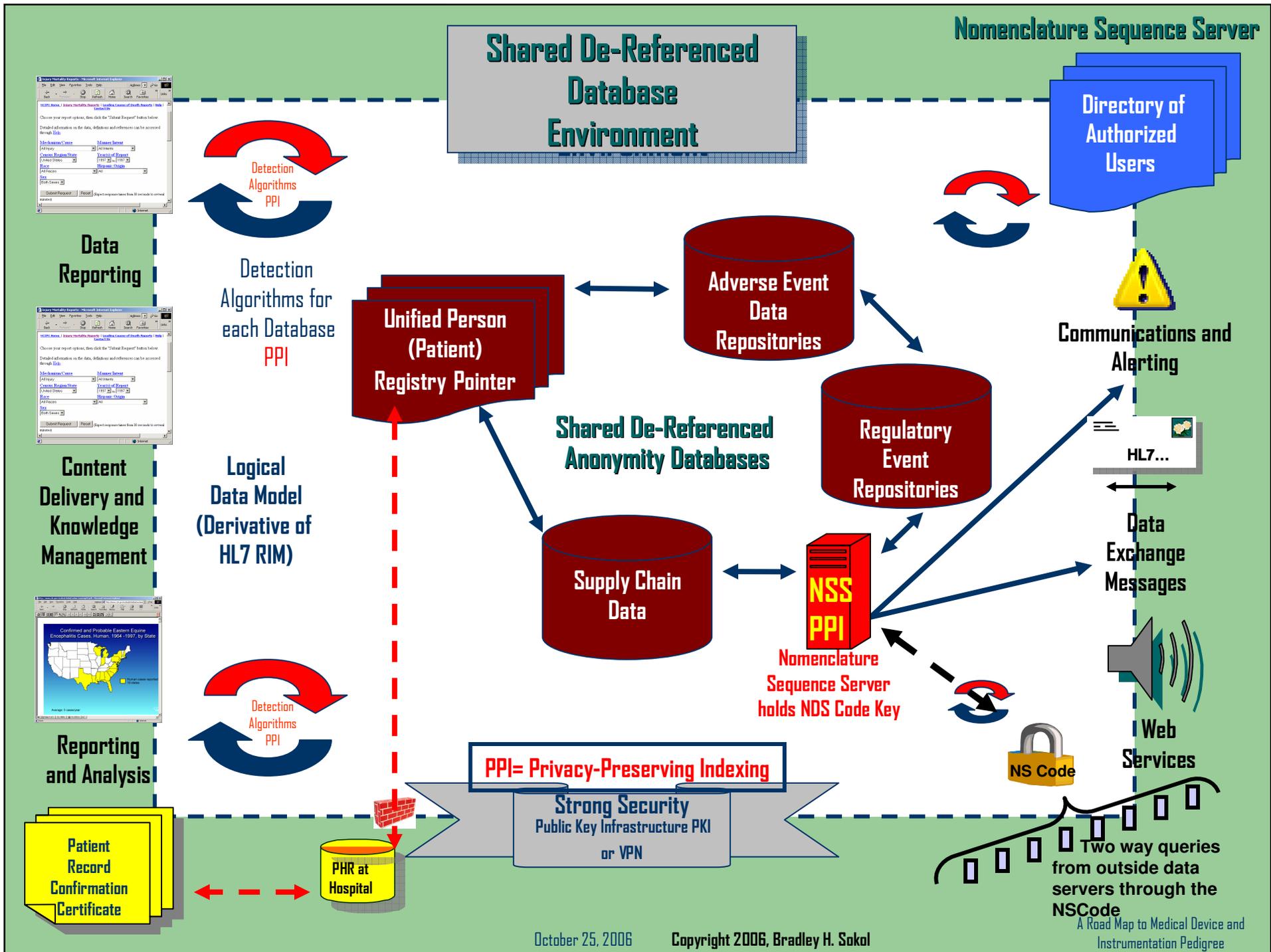


# Keys & Rules



# Supply Chain Members

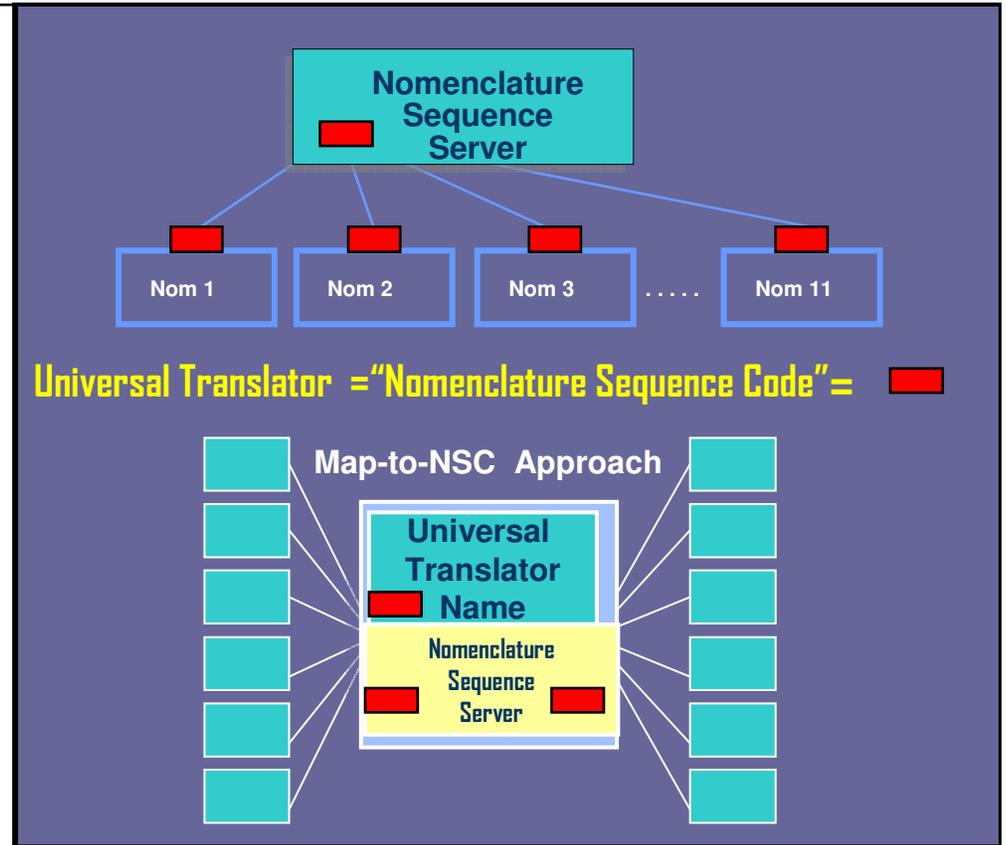




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## Nomenclature Sequence Code: NSC

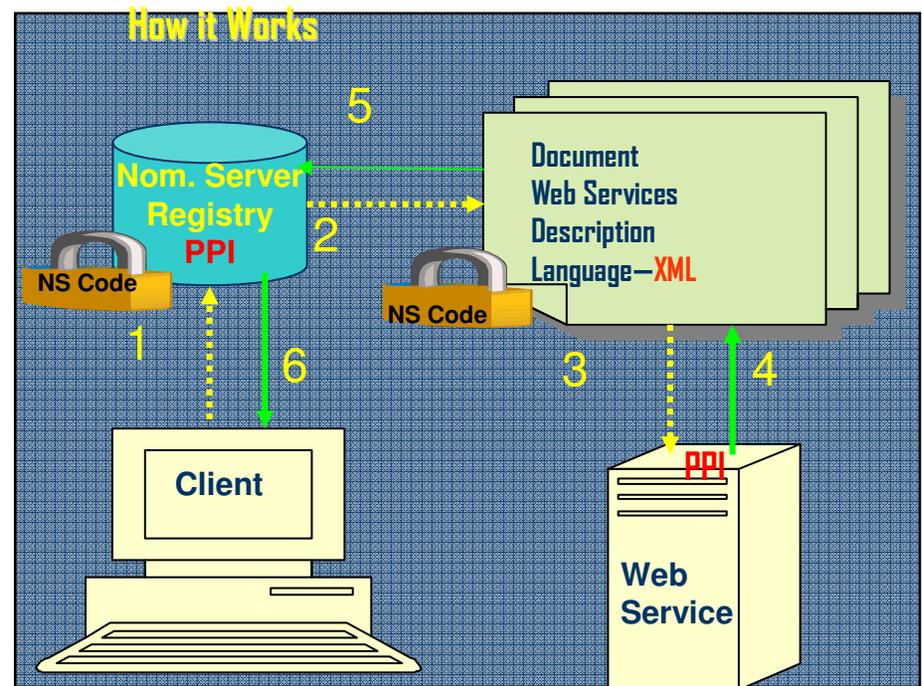


- A rules based metadata naming system; master code (*universal translator*) that combines similar data concepts in different language formats.
- When the language formats' data element's have been mapped to the NSC, A unique data element can be assigned to the NSC
- The NSCs' data element can than point to multiple historical events within the community of database language formats.

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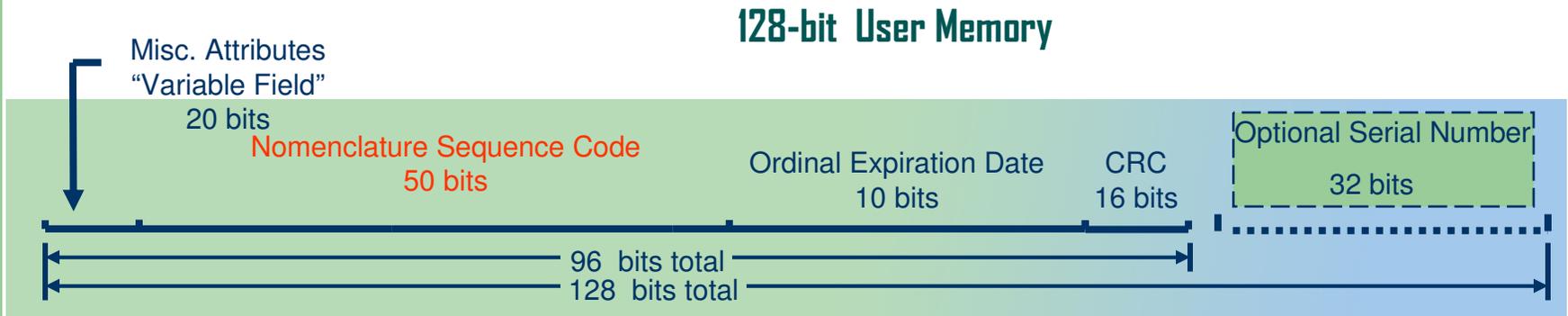
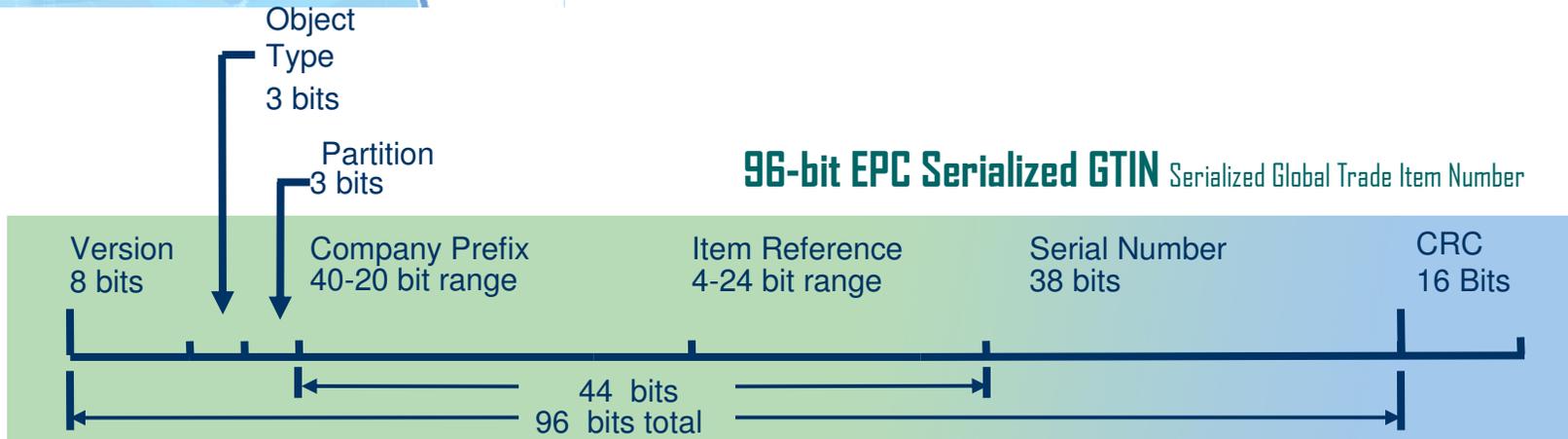
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## Nomenclature Sequence Server (NSS)



- A Secured De-Referenced Registry Database that receives and sends queries as prompted by the NSC.
- This server is the gateway clearinghouse conduit to several other highly classified and secure databases.
- It operates in a secured virtual black-box server environment using Privacy-Preserving Indexing (PPI) [http://www.almaden.ibm.com/software/quest/Publications/papers/vldb03\\_ppi.pdf](http://www.almaden.ibm.com/software/quest/Publications/papers/vldb03_ppi.pdf)
- Assures Confidentiality, Integrity, Authentication and Publisher Anonymity

# Nomenclature Sequence Code: NSC



User Memory

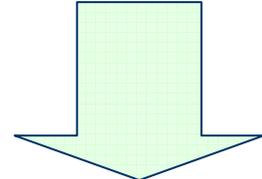
User Memory

96 Bits

Optional 32-128 Bits  
Closed-Loop Applications

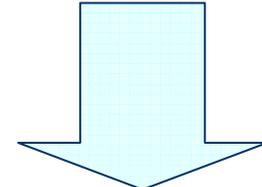
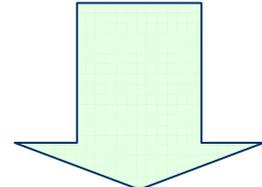
CRC	Variable Misc. Attributes	Nomenclature Sequencer Code	Expiration Date
16	20	50	10
64K	65,535-64K	2 to the 50 <sup>st</sup>	1K

Serial Number
32 avg. (8-160)
2 to the 280 <sup>th</sup>



Universal Item Data Reference Element

Item Reference



Nomenclature Sequencer  
5 layers of 3 digits

Shelf Life

Variable fields, up to 3 separate, event entries-denoted by Y/N Flags or numeric flags for Adverse, FDA approval, Sterilization Cycle # , Clinical attributes Recall, Rented, Loans Reprocessing. Points to other tag fields

Tag Tested: PHILIPS- UCODE EPC G2 - 128 user Memory

For individual item tracking  
Allows for 2 alpha numeric characters  
32k numeric.  
1<sup>st</sup> 3 digits for Sterilization Cycle Verification Reprss. serial#  
Loan/rent/ customer #

Use Case: 256 EPC Compliant DDD Data Construct proposed Passive RFID Architecture & Data Structures May 13, 2004: Nicholas Tsougas: DDD AIT Office [www.dodait.com/conf/jpt/0504/Day2/02-EPC%20data-DDD%20AIT%20IPT%20Brief-%20May%2004%20v1.pdf](http://www.dodait.com/conf/jpt/0504/Day2/02-EPC%20data-DDD%20AIT%20IPT%20Brief-%20May%2004%20v1.pdf)

# Reprocessing, Rental, Recall and Loaner

●..... User Memory 128 Bits .....

## Steps for 3 R's and a L

1. Original product Mfg. serial # stays the same
2. Misc. Attribute field is activated for respective event.
  - a. Y/N or Numeric entry up to 3 numbers
3. Serial # assigned from Distributor Database
  - a. Nom. Seq. Code is updated to point to respective data base
    - i. Optional User memory field could include new serial # or code
4. Write to tag
5. Product received and Public (Regulatory) and Private databases updated

Optional 32-128 Bits  
Closed-Loop Applications

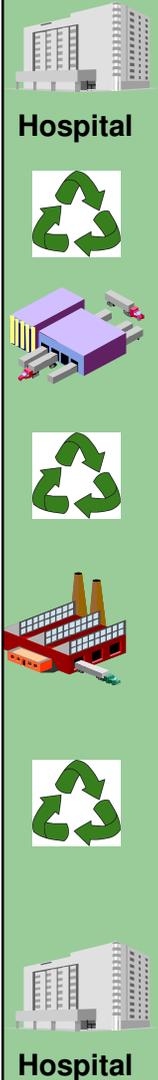
Variable Misc. Attributes	Serial Number
20	32 avg. (32-160)
5 event entries	2 to the 128 <sup>th</sup>

Regulatory Compliance Verification

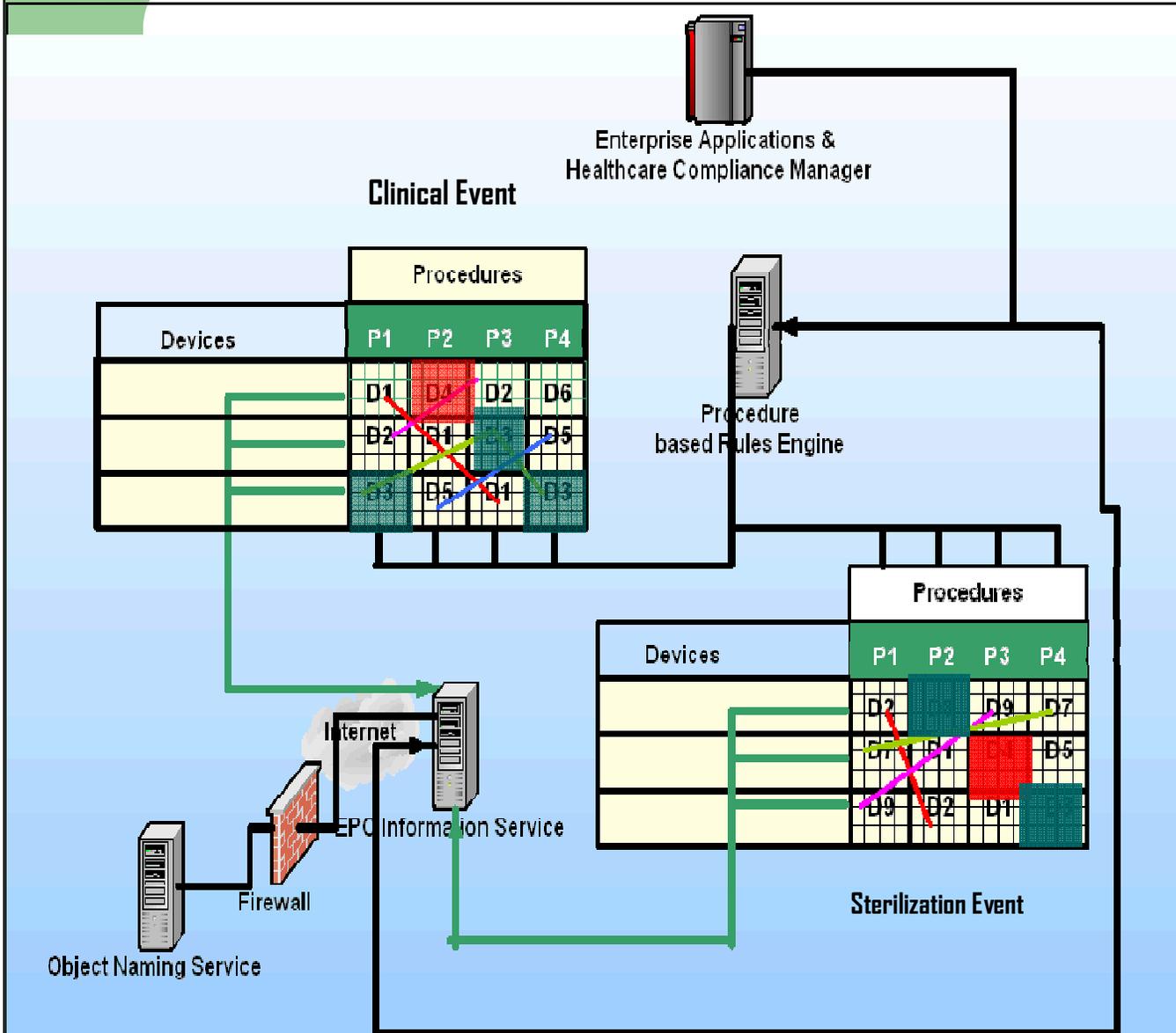
Cost of Data Ownership

Variable fields, up to 5 separate, event entries- denoted by Y/N Flags or numeric flags for Adverse events, Maintenance Cycle # Rented, Loans Reprocessing.

For individual item tracking  
Allows for 4 alpha or 7 numeric characters.  
1st 3 digits for Sterilization Cycle Verification  
Repress. serial#  
Loan/rent/customer#



# USER MEMORY for Sterilization in a Closed Loop



## User Memory

Closed-Loop

Variable Misc. Attributes	Serial Number
20	32 avg. (32- 128)
5 event entries	2 to the 128 <sup>th</sup>

Regulatory Compliance Verification

Cost of Data Ownership

Variable fields, up to 5 separate, event entries- denoted by Y/N Flags or numeric flags for Sterilization Cycle #, maintenance Rented, Loans Reprocessing.

Tracking of each Sterilization Cycle uses the 1st 3 digits to count each cycle