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Guidelines for the Use of RFID Technology in Transfusion Medicine

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Conflicts of interest

Bruce Wray is an employee of Computype, Inc., which is a provider of RFID and barcode products and services. Ian Henderson works for Savant Ltd who supply IT systems to blood services. Clive Hohberger holds less than 10,000 shares (< 0.0002%) of stock and stock options in Zebra Technologies Corporation, which manufactures and sells bar code printers and RFID printer encoders for use in blood banking, but it is improbable that he would accrue any material financial gain or loss. Jerry Holmberg is a Senior Advisor for Blood Policy for the Assistant Secretary for Health in the US. He also serves in an advisory capacity to the RFID Steering Committee of the BloodCenter of Wisconsin. This has been reviewed by the US Government ethics officer and found acceptable. There is no financial relationship with the RFID Steering committee and Bloodcenter of Wisconsin. All other authors have declared no conflicts of interest.

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GUIDELINE

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Guidelines for the Use of RFID Technology in Transfusion Medicine

Part I: General Information

1. Background

The first application of RFID (Radio Frequency IDentification) was in World War II by the United Kingdom's Royal Air Force to identify their airplanes. Today there is renewed interest in the technology as its reliability has improved and its costs decreased. RFID technology is now reliable enough to support the optimization of production processes, health care services, and security control. After reviewing the results from initial RFID trials, the International Society for Blood Transfusion Working Party on Information Technology (ISBT WPIT) voted in 2006 to create a Task Force on RFID to review the current state of RFID development and recommend guidelines for the use of RFID in transfusion medicine.

1.1 Purpose

Implementation of RFID in health care is primarily driven by a desire to improve patient safety and enhance the efficiency of the supply chain. This guideline, following a short technical overview and some examples from industry, assesses high level advantages and disadvantages of using RFID in transfusion medicine and identifies specific areas where RFID solutions might beneficially apply. It then provides recommendations on standards that should be considered in future implementations to ensure consistency and compatibility within our industry.

1.2 Scope

The guideline is written for all those who are interested in using RFID in transfusion medicine. It covers the use of RFID in the blood product supply chain from bag manufacturing to the donor and to the patient. The authors are open to all comments, ideas for improvement, and constructive criticism of the first edition.

2. What is RFID?

2.1 RFID Overview

Radio Frequency IDentification (RFID) is a method of uniquely identifying items that uses electromagnetic radio waves (wireless air interface) to interact and exchange data between tags and readers (Fig. 1). There are defined standards (see 10.3.2) to ensure the interoperability of all components.

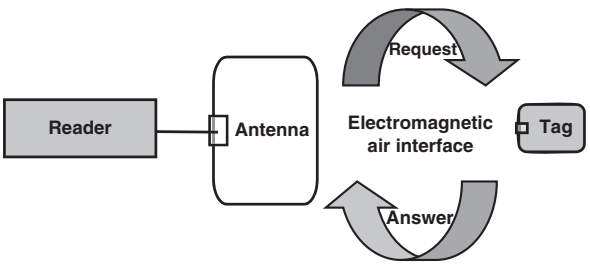

Fig. 1 Communication between reader and tag.

2.1.1 Transponder Tags

RFID tags consist of a chip or small circuit board coupled to an antenna. They are available in many standard forms, shapes and sizes, and special designs can be made for individual applications (Fig. 2). Nearly all transponder chips have a factory-programmed **Unique Tag Identification Number (UID).** There are different types of tags distinguished by technical construction and memory function:

Technical Construction

Passive tags receive power from the reader that prompts them to communicate with the reader. The distance at which a passive tag can receive sufficient power from the reader to power up the chip defines its range. Passive tags are the most widely used type of RFID tags.

Semi-active or *semi-passive* tags contain a thin battery to power the chip. Battery power can be used to increase the tag's read range of the RFID tag or, in the case of sensor tags, to enable measurement, analysis and storage of sensor data.

Active tags use a battery to power both the receiver and a transmitter within the tag. Battery power allows the tag to emit a signal without activation by the reader, support a sensor and/or increase the communication range between reader and tag. Beacon tags are used for real-time location detection of a tagged object such as a car, shipping container or medical equipment. These battery-powered tags emit a short message containing identification codes and other object attributes at regular intervals enabling position detection through reader triangulation or other locating methods.

Memory Function

Read-only: ''write once tags''. This includes both tags that are pre-programmed at the factory and tags which may be programmed once only by the user.

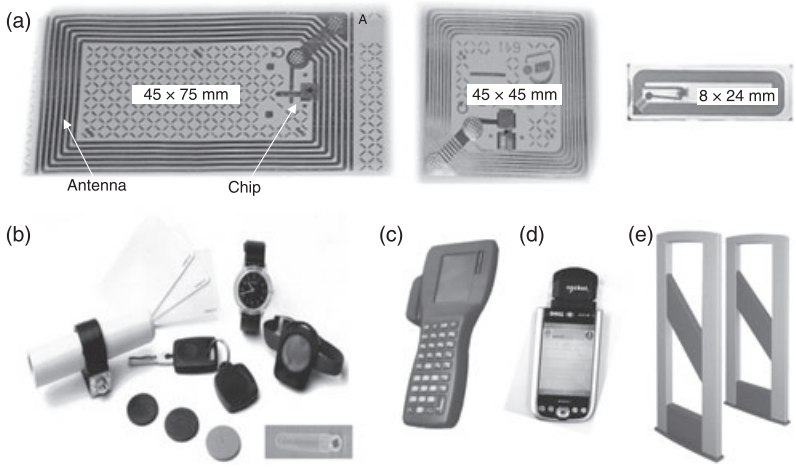

Fig. 2 Different tag and reader designs: (a) Radio Frequency IDentification (RFID)-labels in different sizes, (b) tags integrated in plastic chips, keys, wristbands, glass bottles and laboratory tubes, (c) handheld with barcode and RFID reader, (d) PDA with RFID reader module, (e) gate reader.

Read/write: includes a chip with designated memory blocks that can save and update user-defined data at different stages. Some read/write tags have permanently lockable or password-protected memory that prevents accidental alteration of key data.

Kill command: an RFID special command designed for permanently erasing the memory and disabling the tag so that it cannot be read by any reader.

2.1.2 Readers

Readers have an antenna that sends and receives electromagnetic waves to exchange data with the tag. Power for operation comes from a main or battery power supply depending on the reader type. Some readers are designed to read and show tag information only; others include a processor to run software on the reader. The received information can be sent to servers directly through docking stations, or via wireless networks. There are many types of reader designs and functionalities that are optimized for use as handheld readers, stationary readers, reader gates, tunnels, and equipment-integrated readers (Fig. 2). Some handheld readers are available with barcode reading capability in addition to mixed data carrier usage. Gates and tunnels often allow the identification of individual tags in a group. Very fast reading of all UID in a group is called "*inventorying*" or "*bulk reading*."

2.1.3 Frequencies

RFID systems can work on different frequency bands (Fig. 3):

Low Frequency (LF); unlicensed use is allowed in most countries but there are, however, differences in practice. Typically, frequencies at 125 or 134 KHz are used.

High Frequency (HF) at 13.56 MHz is available for unlicensed use in nearly every country, because of the development and wide deployment of ISO-standardized contactless financial smart cards and an increasing number of passports using RFID technology.

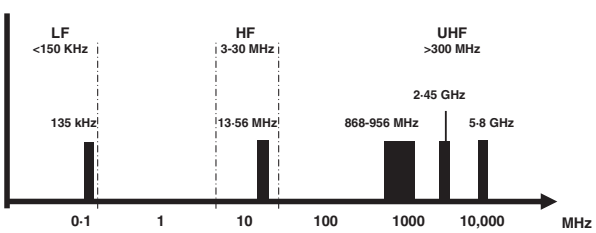

Fig. 3 Allocated radio frequencies used for Radio Frequency IDentification (RFID) technology (LF, low frequency; HF, high frequency; UHF, ultra high frequency).

Ultra High Frequency (UHF) covers the widest range of frequencies. Because of conflicts with assigned cellular telephone frequency bands, UHF tags use different frequencies in Asia, Europe and the Americas. Most major countries approving unlicensed use have some spectrum allocated between 860 and 960 MHz. These tags have the longest range because of the power levels allowed. Allowed power levels in radio regulations for unlicensed use of 2455 MHz vary dramatically, largely because of health and safety concerns in different countries (Note: this frequency band is shared with other types of devices including wireless LANs and microwave cooking ovens).

The physical and operational properties of RFID systems and how these are influenced by biological materials is dependent on the frequency and power levels used (Table 1). The read range is influenced by the form of the tag, type of reader, frequency used, and environment. Because the readers (and active or beacon tags) employ active radio transmitters, the use of RFID tags is subject to governmental radio broadcasting regulations.

Table 1 Characteristics of frequencies used and some usual applications

Frequency	Read range	Coupling method; Biological influence	Applications
Low frequency	0.1–0.3 m	Magnetic field coupled; low impact by water and cells	Personnel access control, storage administration, animal identification
High frequency	0.1–1.0 m	Magnetic field coupled; weak impact by water and cells	Transfusion medicine; medical and pharmaceutical items; "smart cards" for identification and financial transactions; transit passes; logistics and asset management; anti-theft electronic article surveillance
Ultra high frequency	0.1–10.0 m	Electromagnetic field coupled; range strongly affected by water and cells	Case and pallet level supply chain logistics; auto and sea container tracking; automatic toll collection

2.2 Automatic-Identification and Data Capture Methodologies

Automatic Identification (Auto-ID) encompasses a host of technologies that help machines identify objects or persons. It is often coupled with automated data capture and so the term Automatic Identification and Data Capture (AIDC) is commonly used as a technology umbrella. AIDC systems may include barcodes, RFID, magnetic stripe cards, smart cards, optical character recognition (OCR) and biometrics among others. Linear barcodes are ubiquitous in transfusion medicine today. There are defined standards for several Barcode formats (see 10.3.1).

Linear Barcode symbologies use parallel black lines and white spaces of varying widths. A number of standardized symbologies are used such as Codabar, Code 128, Code 39, etc. The current standard linear barcode for use within transfusion medicine is Code 128, referred to in this context as ISBT 128 [1].

Multi-Row Barcodes exploit the principle of linear barcode symbols but feature multiple rows capable of containing up to over a thousand characters and in some cases can be further expanded for data capture functionality. Examples of symbologies used are Codablock and DataBar.

Two-Dimensional Barcodes (2D) are complex printed forms with a high capacity of characters that support error detection and correction so that even damaged symbols can be read. These codes require image scanners to read them. A single 2D barcode can hold all the information currently held in multiple linear barcodes. Symbologies used are Data Matrix, PDF 417 and MaxiCode. The current standard 2-D symbology for use within transfusion medicine is DataMatrix.

RFID and barcode technologies have different characteristics (Tables 2, 3). The strengths and weaknesses of each technology must be evaluated together with the context of the application and the implementation environment.

3. Advantages of RFID Solutions

3.1 RFID Solutions in General

Although RFID technology has existed since World War II there has only been a surge in development of commercial applications within the last 10–20 years. The primary reason for this is that the development of integrated circuit technology has resulted in higher storage capacities, quicker data processing and lower tag costs leading to new opportunities. Another reason is the increase in throughput of materials and goods because of improvements and innovations in the manufacturing process.

Printed barcodes remain the most widely used AIDC system to identify materials in processing systems. They are cheap and reliable, but with demand for increased speed and higher throughput the reading of these codes can become a limiting factor and therefore new solutions may be required. RFID provides a more rapid reading technology that does not require line-of-sight and can operate over longer distances. In some industries, the benefits have already been realized and commercial applications are in routine use (Fig. 4).

3.2 RFID Solutions in Healthcare

In health care environments, the potential for improving safety through better process surveillance and reducing human error, together with the possibility of more efficient treatment processes, has led to a number of trials of RFID applications.

However, despite a recognized potential for improvement in patient safety, RFID technology deployment in health care is limited beyond generic supply chain applications. It is only recently that significant specialized health care applications have emerged. It is likely that this is because of a number of factors, including:

Table 2 General capabilities and limitations of barcodes and Radio Frequency IDentification (RFID) technology

	Barcodes	RFID (13.56 MHz)
	Low cost Widespread utilization 2D barcodes with high capacity for data storage Standards (e.g. ISBT 128) in place	Line-of-sight not required Different data storage capacity, forms and functions are possible, depending on tag design Information can be modified on read/write tags Multiple items can be read simultaneously with special tunnel reader Signals pass through opaque materials Reusable Existing data structures (e.g. ISBT 128) can be used Sensor integration
	Data transmission is performed optically, clear line-of-sight required Amount of data encoded is limited and cannot be changed Only one barcode can be read at a time Read capability can be affected by dirt, water, and scuffing	Higher costs of media and hardware Tag reading dependent on some environmental conditions Potential for electromagnetic interference must be considered in health care installations Final standards are under development today

- Technical difficulties and capital costs for base infrastructure requirements, especially in hospital environments;
- Unrealistic expectations of the technology;
- Difficult business justification, because of an uncertain return on investment (ROI).

For RFID to demonstrate cost-effective benefits and enhance existing barcode identification, significant technical infrastructure development within the hospital environment is required, which encompasses both appropriate hardware (reader, computer) and the application software enabled to make use of the technology.

However, the possible gains in transparency, patient safety, and productivity appear to justify the development efforts in RFID. The potential is provided for new approaches to solving current problems in health care while the cost of the technology rapidly declines, driven by increased usage in many industries.

As with all data management solutions in general, and in health care specifically, RFID will only be successful if the processes to be supported by it are thoroughly reviewed and appropriately adapted to exploit practically the different functionalities of the technology (Table 4) [2,3].

3.3 RFID Solutions in Transfusion Medicine

In transfusion medicine, RFID has the potential to support quick and easy access to process data generated in the blood supply chain, including collection, manufacturing, testing, release labeling, inventory, and distribution.

This could facilitate and improve compliance with Good Manufacturing Practice (GMP), which requires various levels of process documentation at each step [4–6]. The supply chain of transfusion medicine offers the possibility to implement RFID solutions in a smaller, circumscribed, and well-regulated area of medicine with mainly three products: red cells, plasma, and platelets. Results from several trials carried out highlight the different bottlenecks in transfusion medicine [7–10]. Similar to other implementations in other industries, an ROI in health care can only be generally realized if RFID technology results in improved, integrated work flow solutions (adapted hardware and software) with tangible benefits.

The following examples of application show potential benefits of RFID in the transfusion pathway:

3.3.1 Donor Management

Donor identification cards carrying barcodes or magnetic strips are in use in many countries. Integrating an RFID chip into such cards would allow for additional data storage and easy replacement of data, such as a donor photograph, donation history or address changes in the card.

There is also the potential for process monitoring, whereby an RFID reader in donor management systems and collection devices (mixing scale, apheresis device, etc.) could be used to identify the donor in the pre-donation and phlebotomy process [9,11].

Table 3 Comparison of Radio Frequency IDentification (RFID) technology to linear and 2-D Barcodes in Transfusion Medicine

	RFID (13.56 MHz)	Linear barcode	2-D barcode
Physical size	Various; at 13.56 MHz typically ~48 × 48 mm	Depends on amount of data encoded; more data needs longer symbol	Approximately 15 mm × 15 mm
Data size	Depend on chip; read/write tags min. 1–2 kBit (approx. 200 alphanumeric characters)	Approximately 9 symbol characters per lineal inch (2.82 mm/char)	2335 alphanumeric characters
Lifespan	Passive = 10 + years Semi active = depends on battery life	Years; depending on label materials	Years; depending on label materials
Line-of-Sight	Not required	Required	Required
Read characteristics	High throughput; multiple items in one read also in closed containers with special tunnel readers	1–2 seconds per symbol, reading one by one. Often require multiple symbols	1-2 seconds per read, single symbol can contain all required data
Reading distance	Various, typically 10–20 cm with handheld readers	Various, typically 10–20 cm with handheld readers	Various, typically 10–20 cm with handheld readers
Read capability	Can be affected by fluids	Can be affected by dirt, fluids, and scuffing	Can be affected by dirt, fluids, and scuffing, but 2D codes have a high degree of data redundancy that improves their readability even when damaged
Write capability	Content can be updated	Write once, update requires new label	Write once, update requires new label
Working Environment	Harsh environments; depending on construction susceptible to x-ray, centrifugation, very low temperatures and magnetic resonance	Can be engineered for harsh environments and low temperatures; ice and irregular frozen surfaces may affect ability to scan	Can be engineered for harsh environments and low temperatures; ice and irregular frozen surfaces may affect ability to scan
Encryption	Possible	Limited	Possible
Dynamic Updates	Yes	No, data update requires new label	No, data update requires new label
Sensor capability	Possible to integrate different sensors into the RFID tag and to record the data history	Temperature- and radiation-sensitive labels available; no recording of data history	Temperature- and radiation-sensitive labels available; no recording of data history
Smart storage	Possible in places equipped with antennae	Possible in places equipped with bar-coded locations and uniquely-numbered items	Possible in places equipped with bar-coded locations and uniquely-numbered items
Anti counterfeiting/ Security protocols	Possible with ISO14443	Tamper-resistant and tamper-evident label stocks available	Tamper-resistant and tamper-evident label stocks available
Standards	ISO and ISBT 128 standards in place		
Re-Use	May be possible, depending on application	Not possible	Not possible
Costs and utilization	Higher costs	Lower costs, widespread utilization	Lower costs, widespread utilization
Interferences	Electromagnetic interferences possible	N/A	N/A

3.3.2 Blood Product Management

The application of RFID tags in the blood product management process is seen as an area offering a great possibility for process improvement and could help to realize major improvements in storage and distribution of blood products. If a tag is applied to the blood bag there is the potential to facilitate the product identification during collection, processing and distribution and to monitor storage and distribution of finished goods as long as these remain in the same container. Thus, data transported on the

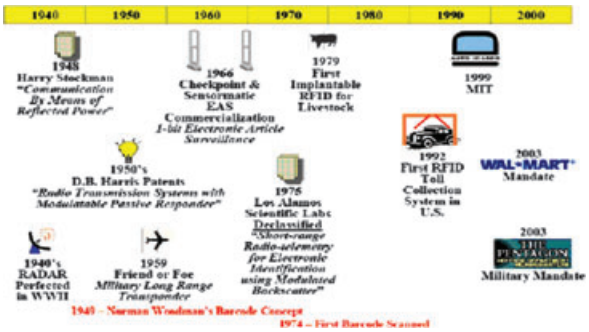

Fig. 4 Milestones in the development of Radio Frequency IDentification (RFID) and barcode technology.

blood bag allows for efficient sharing of information among the different stakeholders (depending on security levels) [3,7–12].

Manufacturer

For blood bags, integrated RFID tags allow the manufacturer to use the UID for identification within their own processes, the assembly of the outer cartons, and their related logistics processes and handling. Further information such as lot number, expiration date and, in the future, possibly the single unit tare could be stored on the tag and shared with the customers. Thus, customers can use the tags for their incoming control management, the release of the goods, and for further processes. In initial trials, only

Table 4 Radio Frequency IDentification (RFID) functionality and the current status of possible adoption in health care (not all are in routine use today) [4, modified]

Function	Description	Current status
Access control	More acceptable than magnetic cards or pin-pads because the tag can be presented in many formats (key fobs, lapel badges, etc.). Enables contactless identification in "sterile" environments and automatic door operation. Can be tied with stored biometrics for access security control	Used for access control sometimes in connection with time management
Bulk reading	Incoming, in-process, and distribution controls of hospital wear, pharmaceuticals, blood, surgical instruments, etc.	Trials with blood, pharmaceuticals, and medical devices
Counterfeit protection	Protection of pharmaceuticals, plasma products, instruments, and devices	Trials with pharmaceuticals
Data storage and transport	Mobile data collection and transport possible in environments without wireless solutions and server connectivity or for quicker recording. In future: data store and carrier for implanted biochips	Some larger trials with tags on blood bags
Identification	Safe identification of Patients during hospitalization time; Laboratory samples by sampling and in lab; Therapeutic agents by assembly and application.	Some large trials with patient wrist bands and application of blood and drugs
Location	Real Time Location System (RTLS) for location of mobile medical devices, blood, location of staff and patients	Limited deployment in US for critical care equipment
Observation and controls	Mentally confused patients Maintenance, cleaning/sterilization control	Applications in place
Process management	Blood banking supply chain, Implants life cycle, Emergency care chain (processes in time), patient guidance, container guidance for food, wear, pharmaceuticals, lift, etc.	Some trials and first applications
Sensory functions, monitoring[a]	Today: temperature monitoring In future: Implantable devices to monitor blood pressure, blood sugar and different metabolic values, etc.	Trials with blood and sensitive pharmaceuticals
Theft protection	Babies, devices, instruments, pharmaceuticals	Some working applications and trials
Time registration	Flexible time management of staff, patient waiting time	Some applications

[a]Needs semi-active or active RFID chips.

the red cell packs were fitted with tags, however for integrated triple or quadruple systems the tag could be used also for the whole blood. Plasma bags were fitted with tags later in the manufacturing process to observe inactivation steps. A future comprehensive solution may need two RFID tags, one for the red cells and one for the plasma bag [3,8,11].

Donation

If blood bag systems with integrated RFID-labels are not available, tags could be added at the collection site. During the donation process, the release of the collection bag set, the bag tare (comparison of the declared with the tare measured at the donation site can detect loss of fluid) and expiration date could be checked by the collection device software. Relevant donation data such as user, time and date, collection period, weight, and in the future, possibly, unique lab tube numbers, etc. could be written to the tag. [3,8,11].

When the Donation Number label is applied to the bag set at the point of collection, a simple hand-held combined barcode and RFID reader may be used to read the ISBT 128 Donation Number barcode [1] and program it and other relevant information into the RFID tag.

Processing

RFID allows automatic identification of the bags within the read range. Major improvements are possible, including the ability for bulk reading and no need for line-of-sight for scanning, which make it easy for employees to perform concurrent manual activities.

Storage and distribution

Quality and/or security checks, e.g. visual controls, specimens for content measuring and so on are often registered on paper sheets; these could be monitored more easily and rules enforcement could be checked at several points within the distribution chain. Similar applications are used today for security and maintenance by companies in other industries. The addition of laboratory data to the tag (e.g. cross-matching, antibody screening) could also offer some significant process control benefits [3,7,9–11,13].

Product turnover could be more easily managed to reduce outdating, and units required to meet specific clinical requirements could be more rapidly located and/or re-allocated, either within the storage equipment or with a mobile reader [3,8–11,13]. Such processes have been successfully used in several libraries for the management of their collections.

During the distribution process, bulk packaging could be checked for completeness and the transmission of shipment information could be done rapidly using the RFID label. Receipt of bulk deliveries in the hospital clinic laboratories could be significantly improved, allowing proof-of-delivery reconciliation, and also providing a rapid means for the incoming components to be scanned and relevant data loaded into hospital information systems [3,7–11].

A far greater degree of automated monitoring of product location may be possible with readers positioned in equipment across the cold distribution chain where it is necessary to know the storage temperature of the products. However, there are difficulties relating to the small ranges and the different storage temperatures. Monitoring of every shipment of bags is currently possible but is inefficient and expensive. The use of semi-active labels with temperature monitoring in shipping cartons allows products to be monitored during transportation [11]. The same label could be used in facilities without central temperature monitoring systems to observe the storage temperatures of red cells and platelets. The low storage temperature of plasma can affect the shelf life of the tag battery.

3.3.3 Patient Identification

Patient identification has relied upon direct inquiry of the patient; referring to notes attached to the patient wristband or performing a bedside test to control the patient's blood group. Verbal statements given in difficult situations are often ambiguous; handwritten or printed wristbands and bedside test-cards can be incorrectly applied or interpreted.

The use of automated identification technologies on wristbands is growing with linear barcodes, 2D barcodes and RFID bands available. The first trials with RFID wristbands showed the feasibility of the technique [13–15], but there are some technical issues with the use of RFID for this purpose. For example, magnetic resonance imaging techniques and, for some kind of RFID tags, x-ray irradiation, have been shown to destroy the information on RFID tags. It will be essential to overcome this limitation.

Other potential applications of patient identification with RFID include billing functions, such as bed side charges for medication, supplies or special care functions; cafeteria services, telephone calls, and pay per view television. Additional possible applications are the tracking and/or guidance of the patient through the hospital, including access control and queue management, and specialized applications for patient monitoring and security, such as psychiatry, dementia care and neonatology [16].

3.3.4 Transfusion Management

For the collection of pre-transfusion blood samples and the transfusion of the blood at the bedside, it is necessary to use unique patient identification and tubes with preprinted unique sample numbers. With barcodes or RFID tags on the patient wristband, the sample tube, and the blood bag, it is possible to cross-check the collection of

the blood sample and later the transfusion process [3,8–11,13–15].

The utilization of sample tubes with embedded or labeled RFID tags in lab management is at present difficult to cost-justify. Currently sample tubes with an embedded RFID tag are primarily being used for long-term storage of genetic material to support tracing of the samples.

3.3.5 Facility and Device Management

Standard RFID solutions are available for access control and time management. Similar to industrial track and trace solutions, RFID tags, sometimes with integrated temperature monitoring, can be used for the logistics of blood container transport [7]. Further applications are being evaluated for using RFID tags to identify medical equipment and devices [17]. In the USA, there have been extensive investigations to address theft protection and misplacement of medical equipment through a special type of RFID technology called Real Time Location Systems (RTLS), which allows for automatic identification, as well as location tracking. The high cost of replacing stolen equipment is driving the search for a more effective solution, similar to the Electronic Article Surveillance theft protection principle employed in some retail stores.

Another application is the control and administration of maintenance and the proper cleaning/sterilization of medical devices. The relevant maintenance work can be noted on the label or the UID can be registered in corresponding control systems when the work is carried out. There will then be a record that the device was at the maintenance facility and/or that the qualified employee serviced the device [16].

Part II: Deployment Information

4. Technical Recommendations

(RFID standards see 10.3.2)

The ISBT WPIT Task Force on RFID recommends the use of passive HF (13.56 MHz) technology in transfusion medicine when applied to blood bags and storage containers. The reasons include:

- Existence of ISO 18000-3, which is a proven, mature standard and technology;
- Regulations around the world provide for standardized access to HF;
- Characteristics of HF support global deployment in blood banks and hospitals;
- Lower cost tags and lowest cost reader hardware of the frequency options;
- No published evidence of adverse effects on blood products and transfusion safety;
- Limited HF radio energy field minimizes the risk of electromagnetic interference with medical devices;
- HF item tags are likely to be widely used in hospital pharmacies.

4.1 Standardization

The use of passive HF (13.56 MHz) RFID technology is supported with global standards including the ISO 18000-3 tag standard and the ISO 15961 and ISO 15962 data encoding rules. These standards are in line with the GS1 EPC Global proposed HF Gen 2 item tag standard for use in pharmaceutical manufacturing, too [18]. ISO 18000-3 is the recommended tag standard in blood banking.

It is essential to use standardized data structures; the data structures defined in the ISBT 128 Standard Technical Specification are strongly recommended for transfusion medicine [1].

4.2 Tag Capacity

Transfusion medicine requires several different tags: blood bag tags, container tags, location tags, tags for personal identification, tube tags, etc. The following design considerations focus on the blood bag tag.

Two approaches can be adopted for the use of RFID on blood bags. The first is a 'license plate' approach where the unique tag identification code (UID) of the tag is associated with the unique donation number/product code in the host computer system and is used for tracking and information gathering within that system.

The second approach is to use the tag as a data carrier to gather information held on the label in barcoded and eye-readable forms. The following criteria should apply:

- Minimum tag capacity is 2 kilobits (2kBit), ISO 18000-3 compliant.
- System redundancy: A tag should contain sufficient data regarding the product to allow stand-alone identification and processing even when back-end systems are not available. It should contain, at a minimum, the same data elements recorded in the ISBT 128 label [1].
- System interoperability:
  - A tag should communicate with readers using the ISO 18000-3 standard communications protocols.
  - Tags should provide data elements specific to the various stakeholders in the transfusion medicine supply chain, e.g. bag manufacturer, blood center and transfusion service. If a required data element does not exist within ISBT 128, users are encouraged to contact ICCBBA to determine if the data element can be developed [1].

4.3 Tag Functionality and Security

The RFID tag will carry critical blood product labeling information. It is therefore essential to ensure the security and integrity of this information through suitable design of the tag as well as the software application that will be handling the data. Key security features are listed as follows:

- Tags will have their own Application Function Identifier (AFI) as designated by ISO 7816. This AFI indicates that the tag contains data structures assigned by ICCBBA for use by the blood in collection, processing, distribution and transfusion.
- The required tag data structures will be identical to those used for ISBT 128 barcode data [1].
- Key data elements on the tag will be written and locked in pre-defined memory blocks, thus preventing updates to these key data elements (e.g. Donation Number; ABO/Rh) once they are written.
- Commands to deactivate/destroy damaged tags and to re-associate a new tag with a blood product will be designed into the tag, readers, and application software.
- Tags may optionally carry internal process control information used in the blood center or transfusion site processing. Data shall be recorded in such a manner that there will be no possibility of confusion with required ISBT 128 data structures [1].

The application design will provide the necessary data integrity and security checks between the Blood Establishment Computer System (BECS)-generated barcode and the RFID tag at critical control points along the supply chain.

4.4 Method of Tag Attachment

RFID tags can be attached in different ways. RFID tags can be incorporated into the base label by the bag manufacturer or they can be affixed on the base label by the blood center, preferably as part of the donation identification number (DIN) label. In both cases, the tags should be affixed to the upper part of the base label to optimize readability without covering any of the manufacturer's data.

It is imperative that the RFID tag is embedded into the bag or 'sandwiched' into the DIN, rather than being applied loosely to the blood bag itself. If the RFID tag is applied by the manufacturer of the blood bags, the adhesive should be the same as is used for the base label. The adhesive inlay used in transfusion is safe for the blood components and will not interfere with the chip. This technique will protect the RFID tag throughout the preparation processes and will preclude removal of the tag. If the RFID tag is applied by the manufacturer, it should withstand sterilization processes (vapor sterilization at more than 120°C, Beta sterilization or Ethylene Oxide).

The location of the RFID tag is also very important in order to avoid damage to the antenna. When the RFID tag is placed under or is integrated in the base label of an empty bag, the operator should take care not to fold the antenna during the centrifugation step.

The method of adhesion should be resistant to centrifugation (up to 5000 g for 22 minutes), preparation processes (separation, filtration, blast and contact freezing) and storage (+22 ± 2°C for platelets, +4 ± 2°C for red blood cells, down to −40°C for plasma).

4.5 Data Structure

It has been assumed that the RFID tag will provide data throughout the lifecycle of the blood bag. The lifecycle for each tag could commence at bag manufacture, continue through donation (but not always - e.g. split packs which may be the start point for a new tag), through component production, issue to hospital, and finally transfusion to patient (or discard). In this lifecycle of the RFID tag, multiple computer systems at various points in the supply chain are likely to be used to read, write and process the RFID tag data.

The RFID tag can act as an electronic data interchange (EDI) carrier between IT systems, although adequate data backup is required to ensure that critical traceability data is not lost if the tag is damaged or discarded. It will be necessary to set out the data structures and method of use so that data can be added to the tag during the lifecycle in a secure manner - in the same way currently used for labels and barcodes at different stages in the process.

This guideline assumes use of data elements provided by ICCBBA in the ISBT 128 data structure [1]. There is flexibility built into the data structure to allow for the use of non-standardized data elements outside the ISBT 128 data structure, although without standard definitions such data could not be globally interpreted. Provision should be maintained for four stakeholders to encode data on the tag:

- RFID Tag Manufacturer
- Blood Bag Manufacturer
- Blood Center
- Hospital Transfusion Service

Each stakeholder will safeguard the integrity, security, and confidentiality of the data it writes to the tag. The system should be sufficiently flexible to accommodate a hospital that collects its own blood. Positioning of data elements may change to optimize the read/write cycle of the tag.

The structure must be able to comply with different scenarios. In some countries or regions, the stakeholders (Blood Center and Hospital Transfusion Service) may be the same organization. In some cases, the tag may be applied by the blood service where a bag manufacturer

does not supply RFID tags as part of the donation set. In some organizations, it may not be possible to provide patient identity on the tag because of data security legislation. As each ISBT 128 data structure is uniquely identifiable [1], it may not be necessary to define an overall fixed tag memory structure but it would probably be more efficient, with respect to IT systems, if a standard structure were in place.

Tag Manufacturers

RFID tag manufacturers encode the UID, which is designed to be unique globally, on the chip. Part of this code is an AFI and for transfusion medicine the code ''BBH'' was requested from the ISO committee. The UID code is unique; therefore, it may be the only data item on the tag that is being read during routine processing.

Blood Bag Manufacturers

ISBT128 provides data structures pertaining to manufacturers of blood bags, namely the 'Container Manufacturer and Catalogue Number', the 'Container Lot Number', and the 'Expiry Date'. The minimum data elements needed are the Catalogue Number and Lot Number [1].

It may be possible to go further than these standards. For example, the current lot number relates to a batch of many units therefore, in the event of a recall, the number of packs implicated can be high. However, if the UID is used in the manufacturing process, considerable benefits should be gained for all parties as it may be possible to limit the scope of a recall.

Bag manufacturer data should be locked on the tag as part of the pack manufacturing operation. It should not be possible to amend this data once written; it should be locked irrevocably.

Blood Centers

ISBT 128 defines data structures for use by blood centers [1]. It will be necessary to align the data structures with the data blocks on the tag. Twelve data blocks are reserved for use by blood centers. Mandatory data includes donation number, product ID and expiration date/time, and ABO/Rh. Donation number should be encoded and locked at the earliest opportunity. This may be as soon as the donation is collected and donation number label sets are applied to the bag set. Alternatively, this data may be encoded when the donor/donation link is made on an IT system. Other collection data could be encoded and locked at the same time. The data blocks reserved for product code and expiration date/time are rewritable to allow for remanufacturing in the same bag, such as irradiation. ABO/Rh is written once and locked.

Blood center data on the RFID tag will normally be locked as part of the shipping process. However, flexibility will be likely to be needed to allow product information locking at any time. For example, a blood center could issue a unit of red cells subsequently irradiated by a hospital. In this case, it would be necessary to allow the hospital to update the product information and, potentially, the expiration date. Alternatively, product data could be locked by the blood center. The locking under such scenarios is likely to require flexibility at a national level.

Because of the limited tag capacity available, it may be necessary to use a Special Testing data structure related to the product being issued. One of the limitations of current linear barcode symbols is that it is difficult to fit special testing data within the available space. The higher memory capacity in RFID tags will provide an alternative solution for a long-standing label space problem.

Hospitals

Hospitals and transfusion services can add data to the tag regarding the intended recipient. Hemovigilance studies show that many serious adverse incidents are because of errors that occur at the patient interface. This is an area where RFID can make a significant difference.

It must be recognized that application of patient data to the RFID-tag will be subject to national patient privacy and data security legislation and may not be permissible.

Where hospitals can add this information, it will be necessary to determine what sort of information is required by the hospitals for positive patient identification. For the purposes of this guideline, it has been assumed that 96 bytes would be sufficient.

Examples of tag structure

The following three examples show how product-specific ISBT128 data structures could be presented on a tag while ensuring that the data is aligned with the four-byte locking blocks (Figs 5–7). Within each colored block, the symbols use the same form as within the ISBT 128 specification [1].

4.6 Disposal

The destruction of passive RFID tags can follow standard biohazard destruction protocols used for blood bags (medical waste incinerators).

If active RFID tags are used on containers, recycling should be addressed to conform with existing recommendations for battery recycling.

RFID tags do not fall within the scope of the EU directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) if the tag is not attached to other electronic equipment which falls within the scope of the WEEE directive [19].

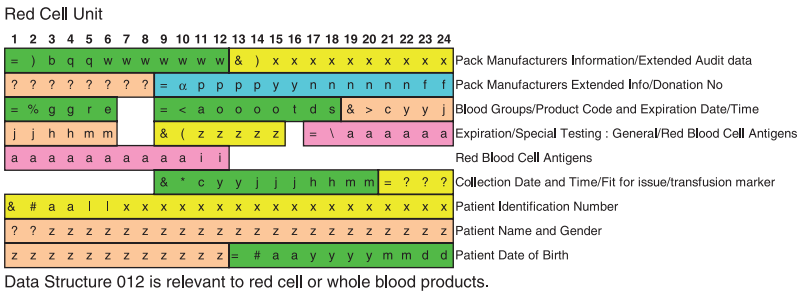

Fig. 5 Red Cell Unit. Data Structure 012 is relevant to red cell or whole blood products.

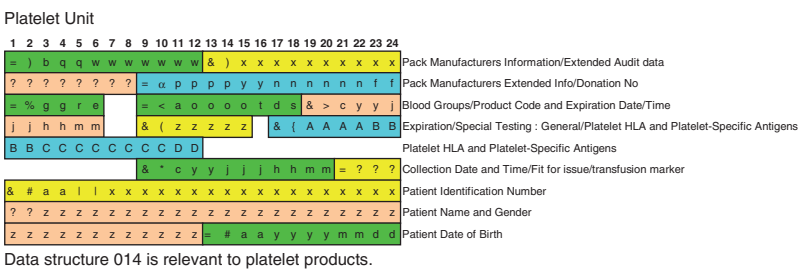

Fig. 6 Platelet Unit. Data structure 014 is relevant to platelet products.

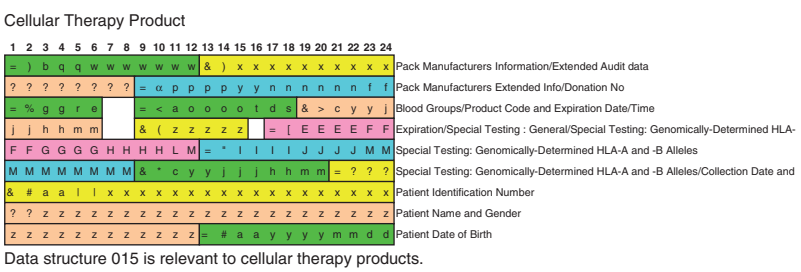

Fig. 7 Cellular Therapy Product. Data structure 015 is relevant to cellular therapy products.

5. Technical Architecture Overview

The RFID-enabled technology for transfusion medicine can be categorized in five high-level layers (domains):

- Business processes
- RFID devices
- RFID middleware
- Enterprise platform
- Enterprise Application Integration

These layers and an overall system representation are shown in Fig. 8.

The Business Process Domain

In the real world physical items move and processes are executed by both machines and people. This therefore creates the demand for information systems to support and optimize processes. Data that is generated and captured requires information systems to turn it into useful transactional information for the execution of those processes; it is aggregated for analysis of trends and process optimization. In order to fully support this domain, additional custom software components (i.e. database schema, user interface, integration between process applications) are needed.

RFID Device Domain

The RFID Device Domain refers to the technical infrastructure of tags, readers and printers. It also includes hand-held RFID-enabled equipment and desktop/laptop computers with user interfaces. It is usually located on the 'edges' of the technical solution interacting with real world items in the Business Process domain.

Tags are affixed to physical items in the business process domain. In the transfusion medicine context, these are blood product items and containers. It is conceivable that

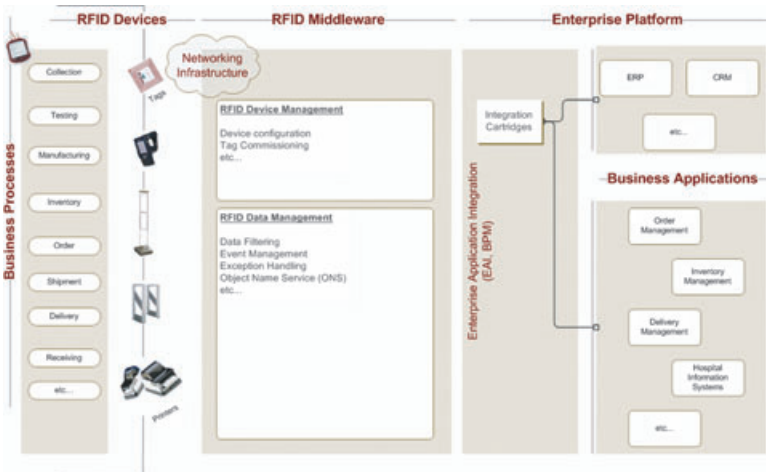

Fig. 8 Radio Frequency IDentification (RFID) blood product tracking (BPT) system architecture.

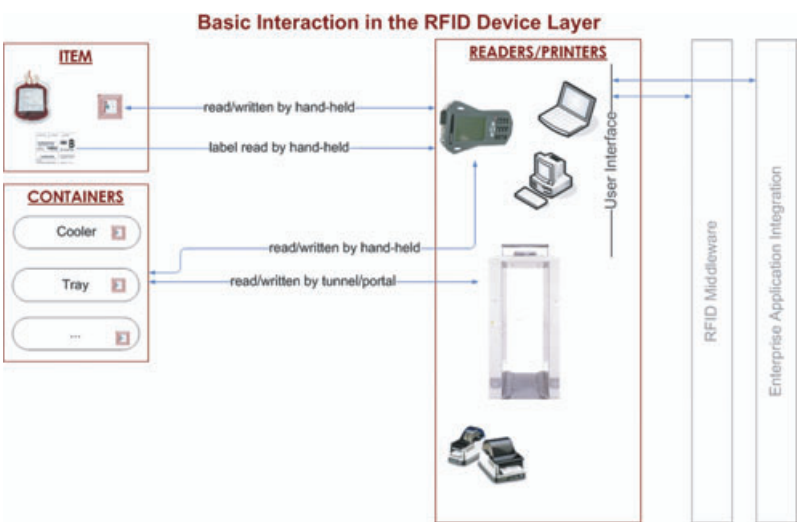

Fig. 9 Radio Frequency IDentification (RFID) device domain.

these tags will eventually be associated with people, including patients or technicians, along the supply chain. For instance, having blood center technicians auto-identified by RFID-tags may alleviate the need for them to manually enter their credentials into particular applications while operating within one of the business processes.

The RFID device domain (Fig. 9) shows the basic interactions performed by common devices in the RFID device layer of the architecture.

Tags used in this environment must have both ''read from'' and ''write to'' capabilities and a user interface to manage the workflow and handle exception situations. The interface may be implemented on a mobile device that has the appropriate application platform or through more traditional hardware such as laptops, personal computers (PCs) and tablet PCs.

RFID Middleware Domain

The RFID middleware domain has the primary responsibility of interpreting the raw 'RFID event' streams in the RFID device layer. It also includes functionality to configure and manage the RFID device network.

An RFID event is simply the reading of a tag in the electromagnetic field of an antenna. The RFID tag may have entered the field of an antenna that is actively scanning for tags, or one that is responding to a command to read tags

(i.e. conducting a 'locate' or inventory function). These RFID events reflect actual activities in the business process domain.

Typical functionalities in this domain include:

- Object Naming Service
- Electronic Product Code Discovery Service (EPCDS)
- Electronic Product Code Information Service (EPCIS)
- Data filtering and aggregation
- Messaging

Some of these services will be interpreted as an application event, whereby the identification of the tag and other necessary pieces of data are collected by the system and passed along to other layers of technology such as order management or inventory management applications that are able to interpret them. This layer will probably need to have interoperability with devices made by several different manufacturers.

Enterprise Platform

The Enterprise Platform generically refers to technical solutions responsible for the enterprise as a whole, line of business applications, and the integration of data. An enterprise application integration layer accumulates messages that pass data from system to system. Enterprise packages and business applications can publish and subscribe to messages, and subsequently act with a transactional command. Figure 10 illustrates how data flows from business process to the enterprise platform.

Enterprise Application Integration (EAI)

The EAI layer is responsible for accepting interapplication messages and publishing to the appropriate subscribers. Consider this example:

- A blood bag passes from manufacturing to inventory;
- The corresponding RFID tag moves from one antenna field to another, thereby creating an RFID event that is captured in the RFID middleware;
- The RFID event is then configured as an event that the system should recognize as an application event. Additional data may be transmitted to the user via user interface. The RFID middleware passes along a message to the EAI layer containing the relevant tag and process information;
- The message is categorized and accumulated in a repository of messages;
- Subscribers to certain types of message categories get notified of the message.

An enterprise solution or Line of Business (LOB) application interprets the message and executes the appropriate transaction or functionality.

Business Applications

Business applications focus on tactical execution of business functionality. They usually align with business processes. For example, systems for managing Testing, Manufacturing, or Inventory are business applications. They are typically stand-alone systems, but may have integration capability such as an application programming interface (API), messaging layer, or direct database access. Enhancements may be required for a business application to subscribe to enterprise messages.

6. Risk Analysis

There are two categories of risks to consider: the general risk assessment and the particular risk of the influence of RF energy on biologicals.

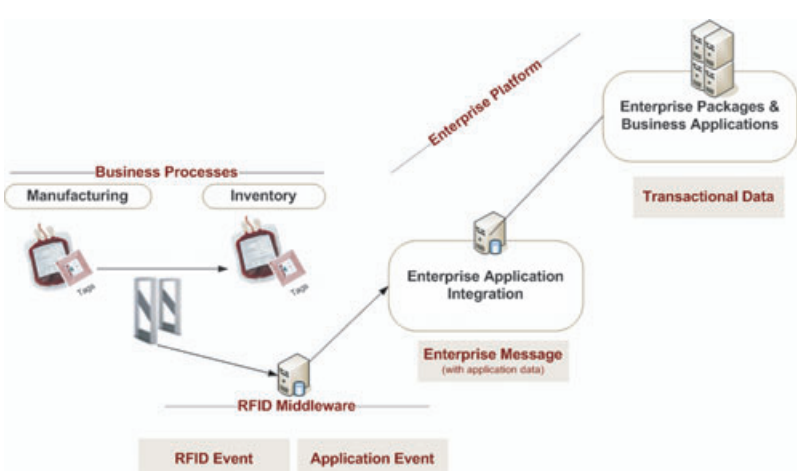

Fig. 10 Basic flow of events and data.

6.1 General Risk Assessment

The following risk analysis focuses on generic use of the RFID tags rather than risks for specific application use (Table 5, 6). It not intended to be a full-risk analysis, but highlights potential risks and possible ways to mitigate or overcome them.

Table 5 Definition of potential risks

Term	Definition
Potential Hazard	Represents potential risks. The list of potential hazards is meant to be illustrative and not meant to be a comprehensive list
Concern	Undesirable outcomes resulting from the hazard
Possible Controls	List of possible controls to mitigate the risk. These ideas are examples; there are a number of different ways to mitigate risk. Risk can be mitigated with the tag or the software that processes the data

Privacy and security risks are also concerns with RFID as well as with any other wireless technology. Those risks must be addressed in transfusion medicine by safeguarding sensitive information and protecting individual privacy. In addition to using the special AFI for blood and adhering to the security standards already implicit in the ISBT 128 data set, the following must be considered:

- Firewalls that separate and protect RFID databases;
- Encryption of radio frequency signals when feasible;
- Authentication of approved users of RFID systems;
- Shielding RFID tags or tag reading areas with metal screens or films to prevent unauthorized access;
- Audit procedures, logging, and time stamping to help in detecting security breaches;
- Tag disposal and recycling procedures that permanently disable or destroy sensitive data.

6.2 Risk of RFID on Biologics

In 2007 the US Food and Drug Administration (FDA) requested that the RFID consortium headed by BloodCenter of Wisconsin (BCW) subject blood products to radio energy under a worst-case scenario to determine whether there was any adverse *in vitro* impact. As it is not possible to test every different RFID configuration, the FDA guidance was to do worst case ''limit testing'' with the assumption that as long as normal RFID operations never approached the tested limits, any impact of the RF reader field exposure on blood safety and efficacy could also be assumed to be acceptable. Limit testing included testing for product heating and key biochemical change outcomes from exposure to an intense RF magnetic field for far longer (23–25 consecutive hours) than would be expected during normal blood banking operations (21 non-consecutive minutes maximum) and at magnetic field strengths (5 A/m = 134 dB μA/m) much greater than

Table 6 Risk analysis for implementation of Radio Frequency IDentification (RFID) technology in general and in health care environments [20–22]

Potential Hazard	Concern	Possible Controls
Tag data lost	Incomplete information	Barcodes on the blood bag and/or Unique Identification (UID) on the RFID tag allow restoration of information from the application and creation of a new tag
Data transmission error between tag and reader	Inaccurate data	Tag communication protocols use Cyclic Redundancy Check 16 (CRC-16) to detect transmission errors
Data integrity on the tag	Inaccurate data	Using CRC-16 protocol to verify proper encoding of the RFID tag Data verification against barcode and ISBT 128 standard
Unauthorized data change	Inaccurate data	Password protection of the tag Encrypt data on the tag Using CRC-16 protocol to verify proper encoding of the RFID tag Use write lock to protect data
Unwanted data	Viruses, Trojans, Worms on the server	Checking the data with the same protection policy as other external devices (CD, Disk, USB flash memory stick) Antivirus software and data firewalls
Electromagnetic interference	Medical device malfunction	Site specific testing prior to deployment as required in existing guidelines on the deployment of wireless communication systems in health care environments If interference occurs increase distance between equipment and RFID device or use Barcodes.

the allowed (126 μA/m = 42 dBμA/m) from an FCC-compliant reader.

The RFID Consortium conducted testing on red cell and platelet products initially, with similar testing for plasma products planned for the future. The testing followed two FDA-approved protocols to assess:

- temperature increase because of RF exposure and
- cellular and/or protein degradation resulting from RF exposure.

Acceptance criteria established for the testing included:

- For red blood cells, the mean hemolysis of both the test and control groups would be ≤1% following 23–25 hours of very high RF exposure (5 A/m^2).
- For platelets, the mean pH of both the test and control groups should be ≥6.2 following 23–25 hours of RF exposure.
- The maximum temperature increase of the TEST unit relative to the CONTROL should not exceed 1.5°C at any period within 23–25 hours of continuous RF exposure.

Cellular/Protein Testing Results

For red blood cells, the mean hemolysis of both the TEST and CONTROL groups was ≤1% following 23–25 hours of (very high) RF exposure (5 A/m). For platelets, the mean pH of both the TEST and CONTROL groups was ≥6.2 following 23–25 hours of (very high) RF exposure (5 A/m).

Temperature Testing Results

The maximum temperature increase of the TEST unit relative to the CONTROL because of Joule heating did not exceed 1.5°C at any period within 23–25 hours of continuous RF exposure.

Test Conclusion

The aforementioned study concluded that exposure to intense RF energy for extended periods has no adverse effect on *in-vitro* cellular integrity of red cells or pooled platelets, nor does it adversely impact the temperature of those products. The scope of the study was limited and did not specifically address impact on aged products nearing expiration. The FDA took no exception to these conclusions and granted permission to proceed with an operational pilot using transfusible blood products.

7. Implementation Methodology

This guideline recommends the Four Phase approach for implementing RFID solutions in blood banks. Further, a change control process including validation and qualification is needed for a safe implementation in health care environments [7].

Table 7 List of supply chain processes to be researched

Blood bank oriented processes	Hospital oriented processes
Blood Donation	Patient Admission
Donation Transportation	Transfusion Ordering
Donation Receiving	Sample Collection
Donation Testing	Patient Sample Testing
Product Manufacturing/Put Away	Cross matching
Inventory Control	Issue and Release
Hospital Order Processing	Transfusion
Order Allocation/Shipping	Product Ordering
Hospital Returns	Retest Product ABO/Rh
Blood Disposal	Assign Product to Available Inventory
	Return Product to Blood Bank
	Product Disposal
	Return Product to Blood Center
	Inventory Management

7.1 Four Phase Approach

A four-phase approach for evaluation, development, and deployment of RFID systems is suggested as depicted in Fig. 11. This four-phase approach is based on research of best practices for systems design and implementation, and has been successfully applied in the context of RFID applications in several industries, including retail, manufacturing, and transportation.

7.1.1 Phase I–The Assess Phase

The primary objective of Phase I is to assess the technical feasibility and impact of using RFID for automatic identification and tracking of blood products throughout the transfusion medicine supply chain. To achieve this objective, the project team should conduct research from both a workflow/process-oriented perspective as well as a technological systems perspective.

Method for Workflow/Process-oriented Analysis

Blood Center and transfusion service processes should be analysed primarily from the point of view of RFID's capabilities for automatic identification, data capture, and tracking of blood products and how the use of this technology can enable redesigned processes that have superior safety, quality and productivity.

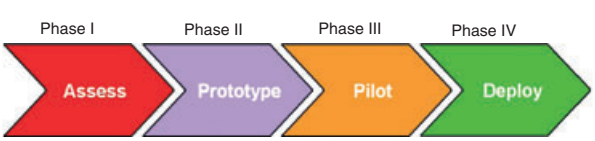

Fig. 11 Four-stage methodology for Radio Frequency IDentification (RFID) system design and implementation. Source: University of Wisconsin RFID Lab.

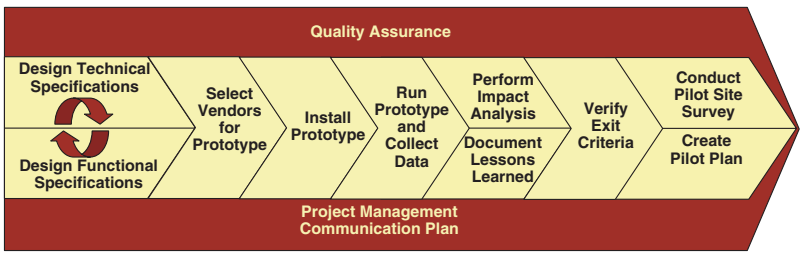

Fig. 12 Overview of the prototype phase.

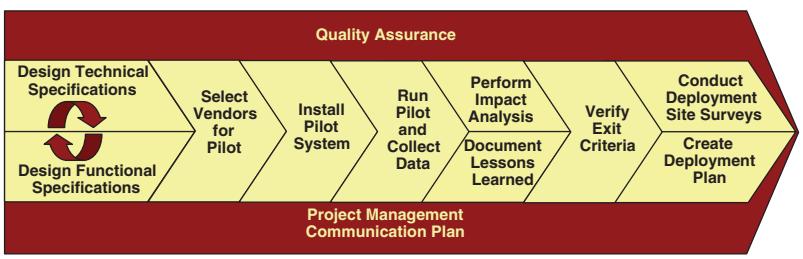

Fig. 13 Overview of the Pilot Phase.

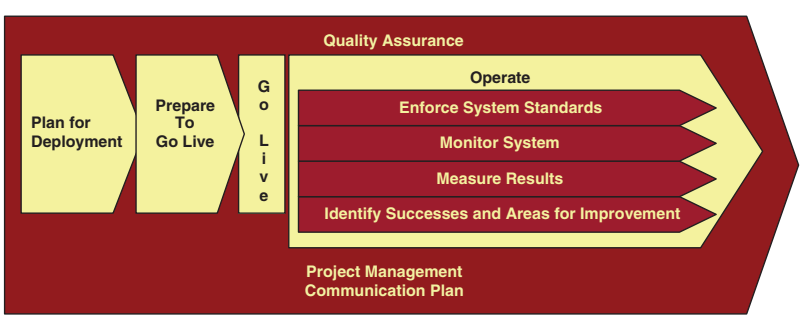

Fig. 14 Overview of the Deploy Phase.

This can be accomplished by mapping existing processes, identifying challenges associated with them, analysing how RFID can enable improvements, and developing redesigned RFID-enabled processes. Processes that might be analysed are listed in Table 7. As a result of this workflow/process-oriented analysis, a set of system requirements to support those improvements should be compiled.

7.1.2 Phase II – The Prototype Phase

The second phase of the project roadmap is outlined in Fig. 12. The objective of the prototype is to demonstrate the functionality and test the limits of the RFID solution in a realistic, yet safe and secure environment that emulates the targeted processes. Performance metrics and necessary check points are identified to evaluate the RFID-enabled processes. Process results are compared and analysed to confirm performance expectations and to discover potential flaws and limitations in the new system.

7.1.3 Phase III – The Pilot Phase

The third phase of the project roadmap is outlined in Fig. 13. The pilot phase involves real processes in limited sites with basic integration to back-end production systems. The pilot phase is methodologically similar to the prototype phase. However, the pilot phase has an expanded scope in terms of processes and back-end integration. All processes included in the new system are placed in actual production in this phase, but for a limited set of sites and products. In terms of systems integration, this phase could incorporate all mainline integration with core back-end systems. The pilot phase could also include collection of performance metrics in order to verify and estimate the anticipated benefits from RFID implementation.

7.1.4 Phase IV – The Deploy Phase

The final phase of the project involves full scale deployment of the systems and processes and is outlined in

Fig. 14. This phase requires rigorous methods for operating and managing the system during and after deployment.

7.2 Tips for Change Management, Validation and Qualification

RFID systems can be used to improve and automate processes and to complement other data management systems. The adoption of an RFID system is a complex process that requires change control documentation, process validation, and qualification of system components to facilitate safe implementation. Today, different templates to guide change management, validation and qualification are readily available.

The ISBT WPIT Validation Task Force published in 2010 the second version of the ''ISBT Guidelines for Validation of Automated Systems in Blood Establishments'' [23]. Its purpose was to supplement existing validation reference material for GMP regulatory compliance, which was more relevant to the field of pharmaceutical manufacturing, and to provide guidance for the application of the validation process for automated systems in blood banking, i.e. systems that have some degree of computer control. The comprehensive re-write of the guidelines has expanded upon the scope of validation activities covered and considered the following developments (see 10.3.3):

- GAMP5®: In 2008 Version 5 replaced Version 4 of the Good Automated Manufacturing Practice Guidelines (GAMP/ISPE)
- ASTM E2500: The ''Standard for Specification, Design & Verification of Pharmaceutical & Biopharmaceutical Manufacturing Systems & Equipment''
- ICH Q8, ICH Q9, ICH Q10: The purpose of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use

7.2.1 Change Control

The change control section of ''ISBT Guidelines for Validation of Automated Systems in Blood Establishments'' describes the procedures used to ensure that changes are introduced in a controlled, co-ordinated manner and are approved by management before implementation [23].

As the first step, the aim of the implementation has to be defined. The reasons for implementing RFID and the possible technical solutions may vary as described in Chapter 3. Depending on these reasons, the following questions in the change control document must be answered:

1. What will be improved, e.g. methods and/or devices (workflow, identification process, patient safety)?
2. What are the possible alternatives from the technical, safety, and financial points of view?
3. What are the affected process steps?
4. Which responsible persons are to be informed and must agree (business and quality management, Qualified Person in EU countries)?
5. Are a project plan, risk analysis, validation and/or qualification necessary?
6. Are key documents, e.g. SOPs, to be changed?
7. Will implementation of RFID result in changes to the regulatory status and/or the manufacturing or testing process of drugs, and must these changes be reported to the authorities?
8. What kind of training is necessary for the staff involved?

Implementation of RFID systems often requires both validation of new processes and qualification of technical components. The risk of any change during validation and qualification, as well as the entire life cycle, must be evaluated, documented, and controlled.

7.2.2 Qualification and Validation

Qualification and validation processes should be used during the full lifecycle of the RFID application through design, development, installation, and operational phases.

7.2.3 Performance Qualification

The objective of performance qualification is to demonstrate that the computerized process will consistently produce acceptable output under normal operating conditions.

This task evaluates whether the aims of the installation are reached, e.g. a reduction in the rate of incorrect transfusions or easier identification of blood products in a process. Another objective of this task is the collection and evaluation of problems and failures such as hardware breakdowns, RFID tag malfunctions, or reader problems. As a result of the analysis, a change in the system or its components may be necessary. This type of change, depending on the complexity and the validation/qualification model chosen, could be documented as part of the performance qualification or in separate change management documentation. Because of the usual extended timeframe of the whole lifecycle, certification of completion of the performance qualification by responsible persons can be difficult and often may require involvement of the direct head of the department or person in charge.

8. Economic Justification and Return on Investment (ROI)

8.1 Blood Centers

A study was done in the USA to assess applicability of RFID in transfusion medicine. Three blood centers in the USA (BloodCenter of Wisconsin, Milwaukee, WI; Carter

BloodCare, Dallas, TX; and Mississippi Blood Services, Jackson, MS), in conjunction with the University of Wisconsin Madison RFID Lab, developed a model to determine impact and return on investment for small, medium, and large blood centers. The model helps assess cost and benefit components involved in implementing RFID-enabled processes and technologies on the blood center end of the transfusion medicine supply chain.

Impact Analysis

The impact analysis study associated with the ROI model was designed to estimate the impact that RFID will have on blood center operations in terms of productivity, quality, and safety. The Impact Analysis consists of three main sections: *Business Profile, RFID-Enabled Process Analysis, and Organizational Impact Analysis.*

The *Business Profile* gives insight into the size, operational volumes, resource availability, and financial parameters of the organization, providing baselines for quantification of both cost and benefits.

The *RFID-Enabled Process Analysis* provides a snapshot of a blood center's current pain points by process, type of event, and the frequency of occurrence. Three types of business metrics are measured: process efficiency, quality, and patient safety. Each organization should develop an estimate of RFID impact on these three dimensions (metrics) noted earlier along with a description of the pain points.

The *Organizational Impact Analysis* quantifies the impact of implementing RFID on an organization's personnel. It gives insight into the effort and resources required to prepare operations staff for RFID implementation in terms of training, communication, and operational impact of implementing new RFID-enabled processes. The training effort on the new processes will be estimated to the point of staff competency and will include a listing of required skill sets. In order to achieve participants' alignment with the new processes, the organization as a whole will require a good understanding of the reasons for the change and the business intent of the technology implementation.

Cost/Benefit Methodology

An Excel-based model has been developed to estimate costs, benefits, net present value, and payback period. The main cost categories included in the model are RFID tags, RFID hardware, IT infrastructure, software, integration, and implementation. The main benefit categories are productivity, quality, and patient safety. Input parameters are collected by surveying processes and technology owners, as well as business systems. Baseline results are calculated for an average medium-to-large-sized blood center (~200 000–250 000 collections per year).

Cost Analysis

In deploying RFID to all operations, the average medium-to-large-sized blood center will experience the following areas of cost over the 5 year planning horizon.

- Start-up costs (Mostly fixed cost - hardware, software, implementation, etc.)
- Recurring costs: Variable (direct cost associated with RFID – usually the largest component and indirect cost).

Benefit Analysis

In deploying RFID to all operations, the average medium-to-large-sized blood center will realize benefits in the following areas:

- Productivity gains
- Reductions in unnecessary discarded product (improved quality of operation)
- Improvement in manufacturing mix.

The model weighs infrastructure and implementation costs, costs over time along with materials, and quantifies benefits from the user of RFID based on the number of blood units collected annually. With the given modeling assumptions, it is possible to project for a medium-to-large-sized blood center the net present value (benefits minus cost) realizable over a 5 -year planning horizon. The model considers the rate of adoption by estimating the number of RFID-enabled blood products added each year to the supply chain. The basic assumption is a gradual rollout of the technology across products and participants. The estimated payback period (years to recover the investment) is then calculated. For a medium-to-large blood center (~200 000–250 000 collections per year), the model predicts a return on investment in 3.9 years. The ROI model reflects results from a broader impact analysis; the ROI for larger blood centers will be achieved sooner and will take longer for smaller blood centers. The models are available from BloodCenter of Wisconsin, Information Services Department, PO Box 2178, Milwaukee, WI 53201, USA.

Additional Benefits

Beyond the benefits that can be financially quantified in the cost/benefit model, stakeholders in the transfusion medicine supply chain can expect additional benefits from RFID enablement. Most notably, an RFID-enabled system will enable an infrastructure for improving patient safety on the hospital side by adding a safety layer against blood/patient mismatches, and potential improvements in process control and efficiency in the Blood Services.

Sensitivity Analysis

Because of the nature of the assessment process and accuracy of baseline data use for projections, it is advisable to perform a Sensitivity Analysis for projections calculated by

the model. This type of analysis is helpful in understanding the effects that variations of data input (positive or negative) into the model input data would have on estimated results. There are many techniques for performing a sensitivity analysis. We suggest beginning with the one-way sensitivity technique because of its simplicity. In the case of the model being described here, current costs were adjusted up and down by 50%. By far, the most sensitive cost area was the cost of RFID tags. Tag cost, if predictions are correct, should decline significantly as RFID use becomes more widespread.

8.2 Hospitals

There are some notable examples of hospitals demonstrating a positive ROI on some RFID projects, such as the Inselspital Bern (Switzerland) where a solution for improving bed management and cleaning demonstrated payback within 2 years.

9. Conclusion

This guideline has focused on RFID solution components and a number of technical recommendations including choice of the radio frequency to be applied, tag capacity, functionality, and data structure to be considered when deploying RFID technology for transfusion medicine. To ensure minimal impact on blood center and transfusion services operations, this guideline recommends the use of passive HF (13.56 MHz) blood bag tags operating on a global standard frequency using an ISO-compliant communication protocol. The minimum suggested memory capacity of 2 Kbits allows use of existing ISBT 128 data structure and messaging. Advice on cost/benefit analysis, risk assessment has been provided. It is recommended that when implementing RFID solutions, a four-phase implementation methodology is used that includes assessment, prototype, pilot, and deployment phases.

RFID adds another layer of safety to the safeguards of current labeling systems. The tag will not substitute, replace, or interfere with any required barcode or labeling information, and RFID software will augment existing blood bank and transfusion systems and not replace them. The tag will be applied on the upper part of the base label, i.e. under the unit number or ABO label or will be provided by the bag manufacturer on the upper part of the base label.

The data structure of the blood bag tag accommodates the needs of all stakeholders in the transfusion medicine supply chain, including: RFID tag manufacturers, bag manufactures, blood centers, and hospital transfusion services. A special AFI for the transfusion medicine industry has been requested from EPCglobal to identify our tags as blood product tags.

The use of RFID in transfusion medicine may streamline supply chain processes by:

- enabling better tracking and reconciliation of products;
- increasing the precision of product locations;
- making it possible to read multiple products simultaneously, and without line-of-sight. This will significantly improve efficiency, increase productivity, and reduce operational costs.

RFID may also increase accuracy of tracking time and temperature and reduce product waste, thus increasing quality and availability of blood products for patients.

And most of all, there is evidence from a number of independent and unrelated studies within transfusion medicine that RFID technology can help ensure appropriate transfusion of the right blood to the right patient, thus reducing errors at the bedside and increasing patient safety.

10. Publications

10.1 References

The authors and collaborators cover different areas of Transfusion Medicine, Blood Bag and Software Vendors, medical and RFID organization, and authorities. A lot of personal knowledge and information as well as information from congresses, conferences and different journals influenced the preparation of the guideline. To cover all these knowledge with scientific publications in a rapidly developing RFID environment is difficult, because many trials, experiences and future opportunities are not yet published in scientific newspapers. On the other hand, all co-workers wanted to publish an ''up to date'' guideline on RFID-technology and transfusion medicine, with a preview about possible future developments to facilitate the RFID-newcomers work and to inspire current users with new ideas. Finally, most references were chosen to give an overview about the actual developments and future opportunities. However some topics are explained based on personal knowledge of the authors.

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10.2 Secondary Literature

(Further references of task members were used for the technical part of the guideline, literature available by the authors)

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10.3 Standards

10.3.1 Barcode Standards

- ISO/IEC 15416: Bar code print quality test specification. Linear symbols
- ISO/IEC 15415: Bar code print quality test specification – Two-dimensional symbols
- ISO/IEC 15426-x: Bar code verifier conformance specification
- ISO/IEC 16022: International symbology specification – Data Matrix
- ISO/IEC 15438: PDF417 bar code symbology specification
- ISO/IEC 16388: Code 39 bar code symbology specification
- ISO/IEC 16390: Interleaved 2 of 5 bar code symbology specification
- ISO/IEC 15417: Code 128 bar code symbology specification

10.3.2 RFID Standards

In recent years several RFID standards including technical documents from the ISO/IEC 18000 series, data standards from ISO/IEC 1569n and EPC Global UHF Generation2 have been defined. These standards are necessary in order to create interoperable systems.

- ANSI/INCITS 256: ,,Radio Frequency Identification (RFID)'', NCITS 256 defines a standard for Radio Frequency Identification (RFID) for use in item management
- ANSI/INCITS 371: ,,Information Technology – Real Time Locating Systems (RTLS)''
- ANSI/MH 10.8.4: ,,RFID for Returnable Containers''
- AWWA IMT61457: ,,The Use of Mobile and RFID Data and Field Force Integration in a Major Water Utility''
- CEPT T/R 60-01: ,,Low-power radiolocation equipment for detecting movement and for alert'' (EAS). Technical Recommendation
- ISO/IEC 6346: ,,Freight containers – Coding, identification and marking''
- ISO/IEC 7810: ,,Identification cards – Physical characteristics''
- ISO/IEC 7816: ,,Identification cards – Integrated circuit(s) cards with contacts''
- ISO/IEC 8824-x: ,,Information technology – Abstract Syntax Notation One (ASN.1) – Specification of basic notation''
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- ISO/IEC 9798: ,,Information technology – Security techniques – Entity authentication''
- ISO/IEC 9834-x: 1993/Amd.2: 1988 ,,Information technology – Open Systems Interconnection – Procedures for the operation of OSI Registration Authorities: General Procedures''
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- ISO/IEC 10536: ,,Identification cards – Contactless integrated circuit(s) cards''
- ISO/IEC 14443: ,,Identification cards – Proximity integrated circuit(s) cards'':
- ISO/IEC 15459-x: ,,Information technology – Automatic identification and data capture techniques – Unique identifiers for item management''
- ISO/IEC 15693: ,,Identification cards – contactless integrated circuit(s) cards – Vicinity Cards''
- ISO/IEC 15961: ,,Information technology – RFID for Item Management – Data protocol: application interface''
- ISO/IEC 15962: ,,Information technology – RFID for Item Management – Data protocol: data encoding rules and logical memory functions''
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- ISO/IEC 17358: ,,Supply chain application for RFID – Application requirements''
- ISO/IEC 17363: ,,Supply chain application for RFID – Freight containers''
- ISO/IEC 17364: ,,Supply chain application for RFID – Transport units''
- ISO/IEC 17365: ,,Supply chain application for RFID – Returnable transport items'',
- ISO/IEC 17366: ,,Supply chain application for RFID – Product packaging''
- ISO/IEC 17367: ,,Supply chain application for RFID – Product tagging''
- ISO/IEC 18000-x: ,,RFID for Item Management: Air Interface''
- ISO/IEC 18001: ,,Information technology – Radio frequency identification for item management – Application requirements profiles''
- ISO/IEC 18046: ,,RFID Tag and Interrogator Performance Test Methods''
- ISO/IEC 18047-x: ,,Information technology – Radio frequency identification device conformance test methods'' for ISO/IEC 18000
- ISO/IEC 18092: ,,Near Field Communication (NFC) Interface and Protocol-1 (NFCIP-1)''
- ISO/IEC 18185: ,,Freight containers – Radio frequency communication protocol for electronic seal''
- ISO/IEC 19762-x: ,,Information technology AIDC techniques – Harmonized vocabulary''
- ISO/IEC 21007: ,,Gas Cylinders – Identification and Marking Using Radio Frequency Identification Technology''
- ISO/IEC 21481: ,,Near Field Communication (NFC) Interface and Protocol-2 (NFCIP-2)''
- ISO/IEC 22536: ,,Near Field Communication (NFC) Interface and Protocol-1 (NFCIP-1); RF Interface Test Methods''
- ISO/IEC 23389: ,,Freight containers – read write radio frequency identification (RFID)''
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10.3.3 Validation Standards

- GAMP®5: A Risk-based Approach to Compliant GxP Computerized Systems. ISPE. 2008. ISBN 1-931879-61-3
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Appendix A – Glossary of RFID Terms

[List based on a courtesy of Robert W. Baird & Co.]

[Further definitions: http://www.rfidjournal.com/article/glossary/]

Active RFID Tag – The tag has an internal power source (i.e. a battery or external power), which allows for significantly longer read ranges or/and work sensors. It is primarily used to track large, high-value assets such as intermodal shipping containers, but there are solutions to work sensors too such as temperature control of pharmaceuticals. Active tags are significantly larger in size and more expensive than passive tags.

Air Interface – The wireless communication protocol between the tag and reader is called air interface. Generation 1 protocols include Class 0 and Class 1. Other proprietary air interface protocols also exist. Generation 2 created a standard air interface protocol.

Antenna – Conductive elements designed to radiate/or receive radio frequency (electromagnetic) energy. As part of an RFID system, it is attached to chips on tags and an integral part of a reader.

Anti-Collision – A protocol that prevents tag data from multiple tags in the read area from interfering (colliding) with each other. Also prevents multiple readers in close proximity from interfering with each other. It is a key component to the Generation 2 standard.

Auto-ID - Automatic Identification is a broad term given to a host of technologies that are used to help machines identify objects or persons. It is often coupled with AIDC; e.g. Barcode, Smart labels, Voice Recognition, OCR, RFID.

Barcode - A type of automatic identification technology (see Auto-ID).

Class 0 – Class 0 refers to a proprietary air interface protocol for passive UHF tags. Class 0 is read only, while a subsequent protocol, Class 0 Plus, offers read/write capability. Wal-Mart and the Department of Defense (DoD) approved the use of Class 0 for their supplier mandate requirements. Class 0 is not interoperable with Class 1.

Class 1 - Class 1 refers to a proprietary air interface protocol for passive UHF tags. Class 1 offers read/write capability. Wal-Mart and the DoD approved the use of Class 1 for their supplier mandate requirements. Class 1 is not interoperable with Class 0.

Dual Di-Pole – A tag that essentially has two antennas, reducing the sensitivity to orientation and increasing read capability.

Electronic Product Codes (EPC) – The code that resides on an RFID tag that is unique to each product. The code contains manufacturer and product information as well as an individualized serial number.

Electro-magnetic compatibility (EMC) – EU directive 2004/108/EC regulate everything to do with interference to other equipment [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:390:0024:0037:EN:PDF].

Encoder – Device that transmits and writes data on an RFID tag. Used extensively in printers and label applicators for product shipments. It is also a reader component.

Environmental Factors – Typically discussed with respect to UHF products, which can be affected by many factors including the presence of metal, liquids, significant reader activity, other RF ''noise'', etc. These factors require strict process controls in terms of tag and reader placement.

EPC Global – EPC (Electronic Product Code) Global is an industry-driven association responsible for setting RFID standards creation; formed originally as a joint venture between the Uniform Code Council (UCC) and the Electronic Article Numbering

Association (EAN). EPC Global is responsible for the Generation 2 standard (hardware air interface), Application Level Events (middleware standard) and the EPC Network (as yet to be employed open network for tracking).

EPC (Electronic Product Code) Network – Developed by the Auto-ID center, this Internet-based system allows supply chain participants to retrieve data associated with an EPC. It is administered by EPC Global.

Frequency - The number of repetitions of a complete wave within 1-second. For example, 1Hz equals one complete waveform in 1-second; 1KHz equals 1000 waves in a second. RFID tags use low, high, and ultra-high and microwave frequencies. All frequencies have their own advantages and disadvantages that make them more suitable for some applications rather than for others.

Generation 2 (Gen 2) – The RFID air interface standard for supply chain shipments.

High-Frequency (HF) RFID – RFID products that use the 13.56 MHz band, which is not regulated by any government. This frequency generally allows read-ranges of 4–8 feet and is not affected by environmental factors such as liquid. It is typically used in item tracking applications (pharma and garment).

Hybrid (semi-active) RFID Tag – A tag that incorporates a smaller internal power supply, which is triggered by reader action. After interrogation, the tag resumes a passive stance.

Identifier – A number or some other form of assigning identity to an item. Using in conjunction with a data carrier.

ISO – International Organization for Standardization is a network of the national standards institutes of 148 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is not government affiliated. EPC Global is an ISO member and is seeking ISO approval for the Generation 2 standard.

Low-Frequency (LF) RFID - RFID products that use the 125 KHz band. Products that use this frequency are generally smaller and cheaper as read ranges are short, typically less than 12 inches. Security access and control are typical applications.

Middleware – A specific class of software that offers several levels of functionality. Middleware acts as a data filter, eliminating duplicate reads so that the host system maintains accurate records and is not inundated with excessive data. Middleware also ensures that the RFID data formatting ''maps up'' with the host system data structure. EPC Global recently adopted the Middleware standard, Application Level Events.

Optical Character Recognition (OCR) – Data is in human readable form. Systems are capable of high speed, accurate recognition, handling multiple fonts and distorted characters.

Optional User Memory – Additional bits memory available on a tag that can be used by any member of the supply chain as they see fit (i.e. routing information). It is intended to allow for increased tracking efficiency.

Passive RFID Tag – A type of tag that receives its power supply from the reader upon interrogation. Used primarily in supply chain applications, these tags tend to be small in size and relatively inexpensive compared to active tags.

Pilots – Testing performed by companies seeking RFID solutions, primarily for supply chain applications. Consumer product companies under mandate requirements are seeking ways to increase the value add to themselves in addition to meeting mandate compliance, which requires evaluation of equipment and internal business processes.

PJM RFID technology -Phase Jitter Modulation (PJM). Principle is only used with RFID standard ISO 18000-3 Mode 2 (PJM) at 13.56 MHz. Identifies up to 1000 tags per second. Writes reliably is 128 bit data to tags at 50 tags per second. Could reaches communication speeds of 424/848 kbit per second.

PJM StackTag®, Magellan Technology Pty Ltd, Sydney, Australia

1. Is an RFID tag that can be operated in stacks of many hundred RFID tags without separation
2. Is unique and does not depend on tuned RFID tags to operate
3. Chips and inlets use a unique method to operate on low field strength
4. Inlets are not designed for resonance frequency (most tags have a self-resonance frequency between 14 and 70 MHz)
5. StackTag inlets do not detune by other RFID tags or materials and will operate even on metal or under water
6. Inlets are designed either for range or for maximum stackability
7. Inlet design is easy and as tags are robust to any detuning existing inlet form factors can be used for easy pilot project installation

Portal – A door or other point in a facility surrounded by fixed RFID readers to identify and track the flow of product. Loading dock doors are a typical example.

Reader – Also known as an interrogator. Typically a network-based device and antenna configuration, which reads the information contained on an RFID tag. In passive operations, the reader supplies the tag with power. Readers can be fixed position for loading dock door or other portal applications, or embedded into mobile devices for in store or exception reporting requirements.

Rollout – When pilots provide sufficient evidence of a strong return on investment, companies are expected to deploy (roll-out) the technology into greater parts of their supply chain. This process is expected to result in significant growth for the RFID industry.

Smart Storage – In this context the authors mean smart solutions in storages, which allow the quick and easy finding of a definite unit in storage rooms or cabinets.

Tag – Also referred to as transponder or transponder tag, which is typically affixed to an item for tracking purposes. Composed of a semi-conductor chip and antenna held together in a substrate. Each tag has a manufacturer installed unique identification number as well as additional few bits to many kilobits of incremental memory. Passive tags receive energy from the reader, while active tags have an internal power supply.

Track and Trace - Involves controlling the shipping and receiving process for medical devices, as well as managing assets and inventories within healthcare facilities.

UID – Unique Identification is a US DoD-based numbering scheme to identify a broad range of high-value assets.

UHF (Ultra High Frequency) RFID – RFID products that use the 868–950 MHz frequency band, which is regulated by governments. This frequency allows read ranges of 8–30 feet (2–4 times that of HF), but can be heavily affected by environmental factors, including liquids and metals, mandated by Wal-Mart and the US DoD for supply chain applications.

Write Once Read Many (WORM) – Used to describe an RFID tag that allows only one set of data to be written on to it. It is typically used in applications where security is a concern.

