RFID: RAPID DEPLOYMENT AND REGULATORY CHALLENGES

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Radio frequency identification (RFID) is one of the most rapidly developing sectors of today's information technology (IT) and automatic identification and data capture (AIDC) industries. Organizations are taking advantage of the robust wireless data exchange capabilities of RFID, plus innovations such as "smart labels"[1] and Electronic Product Code (EPC)[2] developments, to complement their existing bar code systems and improve business practices. RFID technology has received heightened visibility recently because of mandates from leading retailers and the U.S. Department of Defense (DoD) to incorporate RIFD solutions into supply chain operations that support those organizations. The Food and Drug Administration (FDA) has issued a report recommending RFID to develop a "drug pedigree" to prevent the counterfeiting of drugs. RFID has also extended into electronic toll collection, manufacturing control and materials management, cargo logistics, and many other areas.

High-profile compliance mandates and cost savings for businesses are the main factors fueling the growth of RFID. According to the research firm Yankee Group, the improved data synchronization and tracking ability of RFID could cut between $2 billion and $4 billion in costs from the consumer packaged goods and retail industries. A study by the consulting firm Accenture shows that manufacturers could reduce their working capital requirements between two and eight percent and reduce inventory levels even more with RFID-enabled processes.

RFID deployment is expected to be substantial. Many market research firms estimate that there will be nearly a tenfold increase in supply chain RFID use over the next five years. The total global market for all RFID systems is expected to roughly double in size in just three years, growing from $1.1 billion in 2003 to $2.1 billion by the end of 2005. Additionally, RFID patents are rapidly being granted. By the end of 2003, approximately 4,300 RFID-related patents were granted, with more than three-fourths of them granted since 1999.

While the indicators show rapid implementation of the technology, there are some regulatory matters of which RFID manufacturers, designers, and operators should be aware. Key RFID regulatory issues include compliance with the Federal Communications Commission's (FCC) rules and regulations, and the probability of multiplying state privacy laws. Ignorance of the law could impede deployment of even the most efficient and well-designed RFID systems.

RFID Mechanics and Advantages

A basic RFID system is made up of three components: (1) one or more tags, each comprised of a semiconductor chip and an antenna;[3] (2) one or more readers; and (3) a host computer system and application software. Data is transferred via low-power radio waves between a tag and a reader, which are tuned to the same frequency. The reader

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[1] A smart label is a product identification label attached to an item that interacts with an RFID reader to provide specific information about the item.
[2] EPC is a simple, compact "license plate" code that uniquely identifies objects (items, cases, pallets, locations, etc.) in the supply chain.
[3] RFID tags are categorized as either active or passive. Active tags have a battery, which runs the microchip's circuitry and broadcasts the signal to the reader (in a manner similar to that of a cell phone signaling to a base station). Passive tags have no battery; they draw power from the reader, which sends out electromagnetic waves that induce a current in the tag's antenna, and powers the microchip's circuits. The chip then modulates the waves that the tag sends back to the reader. Passive tags currently cost between 15 cents and 25 cents each in volumes of a million tags or more. Active tags cost substantially more than passive tags. Although active tags have a read range of 100 feet compared to 30 feet or less for passive tags, companies are focusing mainly on producing RFID systems with passive tags. Consequently, in this essay all references to tags concern passive tags.

sends out a signal, which is received by all tags tuned to that frequency which are present in the RF field. The tags, which can be attached to virtually anything, receive the signal with their antennas, and respond by transmitting their stored data (which can include many bits of information about an item, including serial number, configuration, time the item traveled through a certain zone, etc.) to the reader. The reader receives the tag's signal with its antenna, decodes it, and transfers the data to the host computer system.

Nearly all RFID systems operate on one of four frequency bands, which are key factors in the reading range of, and uses for, a given system.

Frequency Band	Description	Range
125 – 134 kHz	Low Frequency	To 18 Inches
13.553 – 13.567 MHz	High Frequency	3 – 10 Feet
400 – 1000 MHz	UHF	10 – 30 Feet
2.45 GHz	Microwave	10 + Feet

Low frequency RFID is used mainly in situations wherein the tags pass close by the reader. Livestock tracking, card-key, and access-control are typical examples. High frequency RFID is more flexible, and is utilized for applications such as baggage handling at airports and site management (e.g., telecommunications switching, and power and mining facilities), and tracking key assets in health care facilities such as wheelchairs and operating room equipment. UHF is the most widely-used RFID band, due to its robustness and reading range. Key uses of the UHF band are materials management and supply chain tracking. RFID systems on the microwave band are mainly used for electronic toll collection and railroad monitoring.

RFID is not an optical technology and does not require line-of-site between the tag and the reader, which is an important distinguishing feature that gives RFID performance advantages over other AIDC technologies such as bar codes. RFID can function in harsh environments, permit numerous tags to be read simultaneously, and provide a high level of data security. Additionally, RFID tags have the capacity to contain detailed information about individual items, whereas bar codes identify only the manufacturer and the product. Those advantages, and their inherent cost savings, have caused some leading retailers and government agencies to issue RFID mandates to their suppliers.

Industry and Government Mandated Uses of RFID

Retailers

Wal-Mart and Target stores are leading the way in implementing RFID technology for better supply-chain management. With their low-cost business models, those retailers maintain their competitive edge by having highly efficient supply chain operations. RFID has the strong potential to reduce supply chain costs, speed the flow of merchandise from factories through distribution centers and to the retail stores, and to provide consumers with better product availability.

A recent study by the research group Gartner underscores the efficiency and cost-savings inherent in RFID use in supply chains. That study shows that a retailer's use of wireless applications such as RFID would result in a 90% decrease in location errors, 40% decrease in inventory counting time, and 15% increase in productivity. Additionally, RFID can assist retailers in efficiently responding to government recalls by effectively isolating bad batches of goods, which the retailers can then destroy without having to lose large amounts of inventory.

Wal-Mart is one of the most aggressive retailers in implementing RFID. Over a year ago, Wal-Mart informed its top 100 suppliers that it would require them to tag all their cartons and pallets delivered to Wal-Mart's distribution centers by January 1, 2005.

Some of those suppliers have had difficulties in meeting Wal-Mart's mandate, due to impediments in obtaining the needed number of tags, their cost, and technical problems. Consequently, Wal-Mart narrowed its current mandate to require only tagging on cartons and pallets delivered to three of its Texas distribution centers.

In spite of the initial difficulties, Wal-Mart's RFID implementation is making steady progress. For example, its top 100 suppliers are currently tagging at least one product category in their shipments to the Texas distribution centers, and another 38 suppliers have volunteered to work with Wal-Mart to meet its future RFID requirements. Nearly all of Wal-Mart's suppliers have stated that they will cooperate with the giant retailer to implement RFID on their shipments. Moreover, RFID tags will become more available and economical by early 2006 and beyond as manufacturers are expected to significantly expand their production lines.

Target is another retailer leading the way in implementing RFID technology use by its suppliers. Target announced that it will require its top suppliers to put RFID on all pallets and cases sent to "select" regional distribution facilities beginning in late spring 2005, with all suppliers expected to be in compliance with Target's RFID mandate by the spring of 2007.

Wal-Mart and Target eventually plan to require a tag on each item shipped to their stores, which should greatly enhance their supply-chain efficiencies and monitoring of the sales of their products. The retailers anticipate that RFID will save millions of dollars each year on their supply chain operations, which they can translate into increased profit margins at the point of sale, as well as permitting further cutting of prices, which will go a long way in helping them to maintain their low-cost advantages.

The Department of Defense

In August 2004, the DoD issued its policy guidelines for the use of RFID tags within its supply chain. Those guidelines state that RFID tags will be mandatory in DoD contracts issued as of October 1, 2004; those contracts must require that tags be applied to all cases and pallets and to individual high-value items (items that require a Unique Identification code, such as those worth $5,000 or more, or equipment DoD has deemed mission-essential or is within its controlled-inventory stream) shipped to DoD.

The DoD will incorporate its RFID policy into the next update of its Defense Federal Acquisition Regulations (DFARs). Consequently, all future supply contracts with DoD will be subject to those regulations.

The DoD's RFID mandate was originally scheduled to commence on January 1, 2005. However, due to a number of problems, the mandate was pushed back to April 2005. Those difficulties included: (a) delays in finalizing the new DFARs; (b) failure to adequately notify DoD's nearly 43,000 suppliers of the RFID mandate;[4] and (c) the current RFID tag shortage.

Once it commences, the DoD's RFID mandate will occur in three distinct phases. Phase I, currently scheduled to begin in April 2005, will require suppliers to tag cases and pallets of packaged troop rations, clothing, individual equipment, personal items and weapons systems' repair parts and components shipped to two Defense Logistic Agency (DLA) distribution centers in California and Pennsylvania. Phase II, beginning in January 2006, will require suppliers to tag all cases and pallets of subsistence and comfort items, chemicals, petroleum, construction materials, ammunition, pharmaceuticals and medical materials shipped to 32 depots and the two DLA distribution centers. Phase III, beginning in January 2007, will require suppliers to tag cases and pallets of all commodities shipped to all DoD locations.

The DoD has run a number of RFID pilot programs during the past year, and the results have shown that RFID can help to efficiently reduce inventory and better support soldiers in the field. A DoD spokesperson stated that RFID's efficiency in inventory management will help keep weapons systems up and running more of the time, and, at least theoretically, DoD should need fewer weapons systems to have the same war fighting capability.

The Food and Drug Administration

During the past several years, the FDA has become increasingly concerned about drug counterfeiting. Since 2000, the agency has conducted more than 20 counterfeit drug investigations per year, up from an average of five per

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[4] The January 1, 2005 deadline would have applied only to suppliers that renegotiated their contracts in the fourth quarter of 2004. Hence, while most of DoD's suppliers would not have been affected by that deadline, they will be affected in the future as DoD phases in its RFID mandate.

year in the 1990s. In 2003, the FDA commenced a lengthy study on ways to combat drug counterfeiting, and in February 2004 it released a report which concluded that RFID should be used as a major tool in its war on counterfeit drugs.

The FDA's report includes a recommendation that RFID be used by pharmaceutical companies to create a "pedigree," i.e., a secure record documenting that a drug was manufactured and distributed under safe and secure conditions. The FDA concluded that the detailed electronic history of product shipments made possible by RFID should make it very difficult for counterfeit drugs to enter the supply chain. By sealing a bottle at the manufacturing plant, attaching a tag with a unique EPC, and using RFID readers to track it to the wholesaler and eventually the pharmacy, the manufacturer, wholesaler, and pharmacist can ensure that the product is genuine.

The FDA's report implemented feasibility studies and pilot programs designed to speed the deployment of the agency's RFID program. The FDA stated that it would like to see RFID implemented to track all prescription drugs at the unit level by 2007. While the FDA does not specifically mandate the use of RFID, FDA guidelines are typically followed very closely by the pharmaceutical industry.

The FDA recently took additional actions that demonstrate its commitment to the use of RFID to combat drug counterfeiting. In November 2004, the FDA created an internal "RFID Workgroup" whose duties include monitoring the adoption of RFID in the drug supply chain, identifying regulatory issues raised by the use of RFID, and developing procedures for handling those issues.

Concurrent with its formation of the RFID Workgroup, the FDA released a Compliance Policy Guide (CPG) that allows pharmaceutical companies to test RFID with their products without having to request authorization from the FDA. The CPG temporarily lifts, until December 2007, a number of labeling and other regulations for entities using RFID tags for tests and pilot programs. The subject regulations are waived for RFID tests and trials involving inventory control, tracking and tracing, verification of shipment, and finished product authentication; for prescription and over-the-counter finished products.

A number of major pharmaceutical manufacturers recently announced plans to incorporate RFID into their drug packaging. Purdue Pharma has already commenced a pilot program wherein it will place RFID tags under labels for 100-tablet bottles of OxyCotin prescription pain killers. Pfizer announced that it is planning an RFID project wherein it will tag cases and retail packages for shipments to pharmacies by the end of 2005. GlaxoSmithKline stated that it will begin using RFID within the next 18 months on all shipments of at least one product deemed susceptible to counterfeiting.

UHF Gen 2 Specification and a Globalized RFID Marketplace

Until recently, a lack of a harmonized specification - the communications protocol between the RFID tag and reader – threatened to substantially delay the implementation of RFID on a world-wide basis. Vendors adopted various EPC standards such as EPC Class 0 (64-bit read-only tags/96-bit read-only tags), and Class 1(64-bit read-write-tags/96-bit read-write tags), which led to vendor hardware incompatibility, manufacturing capacity constraints, low tag-yield rates, and high tag costs.

In December 2004, EPCglobal, Inc. (EPCglobal), a developer of industry standards for EPC, ratified its second-generation EPC specification for tracking goods using UHF tags. "Gen 2's" performance and compliance features promise to speed global interoperability of RFID. Gen 2 can, for example, accommodate at least 96 bits of information, which will permit a large amount of information to be stored on a tag, and enable customization of content. Compliant hardware will enable the tag to operate with any manufacturer's reader.

Perhaps most important for global interoperability, Gen 2 conforms to the UHF radio regulations of the FCC, as well as those of European and Asian regulatory agencies. EPCglobal has also worked with various international agencies during 2004 to open bandwidth and frequencies in the UHF spectrum so that RFID can operate seamlessly through supply chains across the continents.

The Gen 2 standard will likely stimulate semiconductor and other RFID equipment vendors to invest in developing products able to address one emerging global market for UHF RFID. For end users, that should mean greater vendor

competition, which presumably would push down prices for tags and readers.

EPCglobal plans to seek certification of Gen 2 by the International Organization of Standardization (ISO) early in 2005. One possible sticking point for certification concerns the use of an 8-bit code that would be used to identify the source of data on a given tag. EPCglobal would like to be able to give entities such as DoD its own 8-bit number to separate the DoD numbering system from all other numbering schemes. ISO wants all of the 8-bit numbers to follow its existing Application Family Identifier (AFI) scheme.

The crux of the issue is the allotment of AFI numbers. EPCglobal contends that, under ISO's current numbering system, it would get only 16 of the 256 values possible within the 8-bit number. If ISO does not allot enough AFI numbers to EPCglobal, EPCglobal argues that it will adopt its own numbering system. ISO is currently insisting that EPCglobal's 8-bit code be used as an AFI, which is an important part of other ISO RFID standards (i.e., ISO protocols that describe how different RFID systems coexist across frequencies, geographies, and industries).

EPCglobal is currently working with ISO to resolve the AFI issue. Because entities such as DoD and Wal-Mart are demanding a harmonized worldwide standard, and large U.S. trading partners such as China are reluctant to participate in more than one standards body, it is likely that EPCglobal will make a strong effort to expeditiously reach an agreement with ISO on this matter.

One other issue that could loom large in the Gen 2 rollout concerns intellectual property rights to the protocol. EPCglobal contends that the Gen 2 standard can be used free of royalties. But, Intermec Technologies (Intermec), an RFID systems provider, claims that Gen 2 contains some intellectual property that it has patented. EPCglobal states that Intermec's patents are not essential to the implementing of Gen 2, and consequently the standard is royalty-free.

But, vendors that produce RFID tags and readers based on Gen 2 who ignore the patent issue do so at their peril. Intermec has stated publicly that any company offering Gen 2 products would absolutely be required to obtain a license to use Intermec's intellectual property. Accordingly, any such vendor would be well-advised to negotiate licensing fees with Intermec or any similarly situated patent holder, and users of Gen 2 products should insist that vendors indemnify them against possible breaches of intellectual property rights in equipment or software.

In spite of the possible impediments to Gen 2 implementation, a number of prominent semiconductor companies have completed testing and will soon begin commercial marketing of their Gen 2 tags. Phillips Semiconductors, for example, has announced that it will commence full production of Gen 2 chips by the third quarter of 2005. Texas Instruments states that it will make Gen 2 chips and inlays commercially available by the third quarter of 2005. And, Impinj announced that it will begin manufacturing Gen 2 tags in January 2005. Consequently, it is expected that Gen 2 tags will be generally available in larger quantities and at lower prices by early 2006.

RFID Regulatory Concerns

The Federal Communications Commission

RFID is regulated under Part 15 of the FCC's rules for low-power devices. Since Part 15 devices have a low potential for interference with other wireless devices, they may be operated without a license. Although RFID devices are unlicensed, they must be authorized by the FCC as meeting its radio frequency ("RF") emissions limitations, power restrictions, and other requirements.

Because RFID devices transmit radio waves, they are classified under Part 15 as "intentional radiators." The FCC's rules require that intentional radiators be authorized via the certification process.[5] Certification entails filing an application with the FCC containing: (a) legal information about the filing party and the device; (b) a technical report consisting of, among other things, a block diagram of the device and RF test results (usually conducted by an accredited testing lab) of the device and its components; and (c) an analysis as to how the device complies with FCC

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[5] The FCC's rules provide that other types of low-power devices which produce RF emissions, but do not transmit radio waves, are authorized for operation and marketing by one of two more informal procedures: verification or declaration of conformity.

regulations. The FCC evaluates the application and determines whether the device meets its regulations and would not be likely to cause interference to other devices. With limited exceptions, an intentional radiator may not be operated or marketed prior to receiving certification from the FCC and labeled as FCC compliant.[6]

Part 15 of the FCC's rules provide that intentional radiators operating at different frequencies are subject to different rules pertaining to how they may be operated. For example, operation in the UHF 902-928 MHz band is governed mainly by Section 15.247, which provides that compliant RFID systems typically use a frequency hopping spread spectrum modulation technique in order to benefit from maximum reader transmitted power allowances. That section permits UHF readers to operate at a maximum power of 1 watt, or up to 4 watts with a directional antenna, if they hop across a minimum of 50 channels.[7]

Accordingly, certification and operation of an RFID system are subject to a variety of FCC regulations, and those regulations state that the manufacturer or importer of RFID components is nearly always the sole party responsible for FCC compliance. If, for example, an equipment manufacturer designs an RFID system and it is operated or sold by a vendor prior to certification, the manufacturer, not the vendor, is the party subject to substantial monetary fines and other disciplinary actions by the FCC. But, the operator of an intentional radiator is also affected in the event of an FCC rule violation, as the device must be taken off the market, and extant devices must typically cease operation until they are re-tested and found by the FCC to be compliant with its rules.

The FCC's rules also regulate the modification of unlicensed devices. If an RFID device undergoes a "major modification" (e.g., increasing the power levels or RF emissions), it must be re-certified before it can be operated or sold. A "minor modification" does not require FCC approval, but if such a minor modification inadvertently increases the device's RF emissions or otherwise significantly alters the device and it is sold or operated, the responsible party is subject to FCC sanctions.

Moreover, it is not uncommon for unlicensed equipment vendors to "spy" on the operations of their competitors by monitoring the RF emissions of their competitors' devices and reporting rule violations to the FCC. Those types of disputes can often result in temporary removal of the devices from commerce, expensive modification of the extant devices, and substantial fines by the FCC. Accordingly, full compliance with FCC rules for RFID systems is imperative.

RFID providers wishing to operate abroad should consult with the appropriate communications regulatory agency before importing or marketing equipment, or commencing operations. In Europe, the European Radio Communications Office (ERO) and the European Telecommunications Standard Institute (ETSI) should be consulted, along with the regulatory agency of the host country. In Japan, providers should contact the Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT). In China, the Standardization Administration of China (SAC) should be contacted.

RFID Privacy Laws

Although RFID has yet to be widely implemented, the legal waters are already being tested to determine how much privacy must be afforded consumers by companies deploying RFID devices. In 2004 alone, six states and the federal government introduced bills concerning RFID privacy matters.

While none of those bills was enacted into law, the increased use of RFID by the business community and the FDA's recommendation that RFID be used by pharmaceutical companies virtually ensure that RFID privacy laws will be passed in several states, and perhaps on the federal level as well. The European Union already has privacy laws on the books that require: (a) products with RFID tags are labeled as such; and (b) companies must inform consumers when they gather data on them, and ask for consent to use that data. This means that companies using RFID will be faced with complying with different laws, depending on the states or countries in which their products are sold.

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[6] The FCC permits an unlicensed device to be advertised and operated at trade shows and exhibitions prior to authorization, as long as certain conditions, such as a conspicuous notice that the device has not yet been authorized and is not for sale, are met.
[7] Rules governing the operations of intentional radiators operating on other frequencies may be found in selected sections of Subpart C in Part 15 of the FCC's rules.

The privacy bills that have been introduced so far uniformly concern the collection of personal information by RFID:

- H.R. 4673 (Federal) – Would prohibit the retail sale of any product containing an RFID tag unless the product contains a warning label and the customer is given the option of removing the tag at the point of sale.

- S.B. 1834 (California) – Would permit retailers or libraries to collect information <u>via</u> RFID only in regard to items customers actually purchase, rent or borrow; information cannot be collected on items customers pick up but put back, or what they are wearing or carrying on their person.

- H.B. 32 (Maryland) – Would establish a task force to study privacy issues related to RFID uses by retailers and manufacturers, and whether those uses should be restricted or prohibited.

- S.B. 867 (Missouri) – Would require that any product containing an RFID tag have a label disclosing that information to the consumer.

- B.D.R. 487 (Nevada) – Would require notification to consumers if an RFID tag is imbedded in a product.

- S.J.R. 10 (Utah) – Would implement a study of business practices related to RFID, including the feasibility of disabling tags at point of sale.

- H.B. 1304 (Virginia) – Would require public bodies to conduct a privacy impact analysis when authorizing or prohibiting "invasive technologies" including RFID.

Consequently, as the industry and government mandate timetables requiring RFID tags on individual items grow near, privacy laws are likely to be implemented. Companies utilizing RFID would be well advised to stay current on the state of RFID privacy laws and be prepared to implement business plans that will be able to handle the legal mandates of those laws.

Conclusion

As RFID continues its rapid growth in the global marketplace, opportunities to capitalize on this technology abound. While high-profile compliance mandates by retailers such as Wal-Mart and Target and federal agencies such as the DoD fuel the implementation of RFID, countless numbers of businesses across all market sectors are investigating the cost-saving capabilities of RFID. However, with rapid deployment of RFID on the horizon, it will be critically important to know how to navigate within the regulatory environment. RFID manufacturers, vendors, and users should be aware of, and develop programs to ensure compliance with, the myriad of current and future regulations.

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