

# Hitachi $\mu$ -chip RFID Technology Compatible with Gamma Sterilization

Tests with MDS Nordion reveal  $\mu$ -chip can withstand at least 500 kGy gamma ray exposure

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## ***Executive Summary***

Radio frequency identification (RFID) is a wireless data collection technology that uses radio waves to remotely send and retrieve data contained within electronic tags. RFID is considered a technical leap from barcode in that RFID does not require a visual line of site to be read and the quantity and speed at which data can be collected from RFID tags is an order of magnitude faster than from barcode technology. Some RFID technologies supply data that is unalterable; and that is desirable for RFID-based item authentication programs and pedigree traceability applications among other uses. Barcodes and many RFID technologies for supply chain applications are easily duplicated, cloned or copied.

The medical and life sciences industries produce and use of millions of high value items around the world each day that are critical to patient care. RFID tagging of these items is one area gaining in practical RFID adoption to enhance product manufacturing efficiency, safety, security, and item lifecycle traceability. However, more than 40% of these same single use medical devices are sterilized by exposure to gamma radiation to ensure protection from potentially harmful microorganism contamination. Many of the life sciences and medical industry early experimenters in item level RFID tagging have discovered that gamma radiation levels in typical sterilization cycles permanently damage, or at the very least, harmfully affect the data contained in RFID tags.

Ottawa, Ontario-based MDS Nordion, a leading provider of gamma sterilization isotope and equipment, has been investigating the effects of gamma energy on RFID tags. MDS Nordion and Brisbane, California-based Hitachi America, Ltd. conducted controlled experiments to determine if Hitachi's  $\mu$ -chip RFID technology is adversely affected by gamma energy exposure and to what levels of exposure the basic  $\mu$ -chip inlets (IC chip attached to its external antenna in an unprotected, unruggedized "bare" condition) could typically endure before readability performance is compromised. The test results proved  $\mu$ -chip is gamma resistant up to, and likely beyond, 500 kilogray (kGy) of gamma energy.

Hitachi's  $\mu$ -chip RFID IC chips are slightly different from other RFID IC chips in an important way. In the case of  $\mu$ -chips, the unique and never duplicated identification data contained in each  $\mu$ -chip IC is structurally "hard wired" into the chip. The hardwired code is far less affected by gamma energy.

Gamma energy exposure damage is cumulative. A 500 kGy exposure of the  $\mu$ -chip is representative of 20 typical medical device sterilization cycles of 25 kGy each. The test team concluded that  $\mu$ -chip is fully compatible with current gamma sterilization protocols and considered a highly viable RFID technology for medical disposables and any other items

Page 1 of 11

that routinely undergo gamma exposure, especially repeated gamma exposure. Additionally, the small form factor attributed to its 2.45GHz operating frequency and proven durability of  $\mu$ -chip inlets further qualify this technology as a highly practical RFID inclusion for small or high value items.  $\mu$ -chip inlets are subjected to and survive high temperatures and pressures in processes such as plastics molding and the vulcanization process of rubber. The hardcoded unique identifier in the  $\mu$ -chip makes it especially suitable for traceability and authentication against counterfeiting and grey market diversion as well as in manufacturing process control.

## **What is RFID**

Radio frequency identification (RFID) is a wireless data collection technology that uses radio waves to remotely send and retrieve data contained within electronic tags. It permits transfer of information to and from objects and onward to host systems via radio frequency transmissions. Just like bar codes, RFID tags store data in a machine readable form decipherable by a tag reader (interrogator). Unlike barcodes, RFID tags are more suitable for tracking individual items because the quantity of data contained in a single RFID tag can be large enough in alphanumeric characters to support mass serialization methods and retain a fast read response time. Depending on the specific variations and virtues of the RFID technology employed, RFID tag data can be difficult to copy or alter. RFID imparts the ability to accurately track and trace individual items as tiny as single dose pharmaceutical syringes or as large as railway cars.

Unlike bar codes, no optics are employed in RFID. Therefore, RFID tags are not limited to line-of-sight communications. That is, the RFID reader antennas need not be within visual sight of the RFID tags. The RFID reader antenna needs to be within the read range of the RFID tag usually placed on or inside an item. RFID tag read distances can be as short as fractions of a millimeter or as long as several meters, this depending on the specific RFID radio frequency employed and the air interface communication protocol of the tags being used combined with any radio detuning effects imposed by the item being tagged. Many materials are *RF translucent* allowing RF communications signals to pass through them. An RFID tag usually continues to be readable when placed under a paper label or encapsulated within an item made from most plastics, as an example.

RFID is a wide-ranging technology with great variation in features, functions and price points. RFID for library book tracking is very different from RFID for automated road toll collection, yet both applications serve a similar purpose: to identify a specific item as it passes through a specific portal, then account for the event as a transaction in a back end database. For the purposes of this white paper, the RFID technology discussed is limited to passive, integrated circuit chip-based RFID primarily for low-cost tag business case requirements, and where read-only tag attributes best serve the needs of the application.

Integrated circuit (IC) chips are currently the most common and cost-effective form of high density data storage for RFID tags. Other storage technologies such as radio crystals and printed ink circuits are finding practical and useful ways into RFID tags, but IC chips are, by far, the most commonly used.

The term, passive, means the tags have no on-board power source to assist in RF transmission. Passive RFID tags absorb RF energy from a tag reader's transmit function and convert the RF energy into small amounts of electrical energy. The electrical energy powers up the IC chip in the tag. The IC chip utilizes some remaining electrical energy to transmit back its data payload to the reader's receiver function which interprets the tag's signal into meaningful data strings. With no power source to wear down, passive RFID tags, when properly protected from environmental conditions, can survive indefinitely. There is one important distinction regarding data longevity in writable RFID tags. In writable or re-writable tags, data is stored in the form of electrons held in registers within the IC chip. In binary number code, a "1" is represented by the presence of an electron in a specific register and a "0" by the lack of an electron in a register. Over time, those electrons will fade, and outside energy sources (such as gamma energy) can compromise the tag's data. Read only IC chips, depending on their underlying non-volatile memory technology, do not necessarily tie their data payloads to the presence of electrons held in the IC chip, and therefore could have longer service lives. These RFID chips, such as the Hitachi  $\mu$ -chip, are better suited for archival applications. Hard-coded data RFID tags are better matched to long shelf life applications such as a pathology specimen tracking program demanding tag data remain readable for 10 years, or whiskey barrel tracking during an aging period measured in decades.

Low cost is a relative term, but within the RFID industry, RFID tags under fifty cents are considered low cost. A tractor trailer RFID tag costing \$10 and expected to remain in continuous service for 7 years may be highly cost effective if it replaces a human gate keeper with responsibility to monitor when each truck has left or entered the yard. A 25-cent RFID tag applied to a piece of airline passenger luggage may ordinarily not generate a full 25 cents of value, unless the tag sped up and improved sorting accuracy and prevented hundreds of dollars of expense incurred to the airline to reunite the bag to its owner had the bag been incorrectly routed without the RFID-boosted bag visibility at the airport. Collectively, the sum of the value created by implementing an RFID program needs to be higher than the total program cost, including tags.

Aside from the inherently stable data content of read-only RFID tags, these tags make RFID-based authentication simpler. With a known population of difficult-to-duplicate read-only UIDs, the validation of the item's authenticity is defined by the presence of the valid RFID tag secured on or in the item. Authenticity can be validated at any point in the item's travels in an open supply chain. In other words, if the item leaves the factory with a known RFID UID and that same UID is present in the item at a final or critical validation point and no tampering with the item or RFID tag has occurred, the item's authenticity is proven. In the case of easily copied or cloned RFID tag technology, the item's authenticity is inferred by collecting and analyzing read events of the item at many points during its travels in an unsecure supply chain. Authenticity is dependent on collecting read events from many supply chain members who may have had possession of the item. If the read event transaction pedigree falls within expected ranges, the item is considered valid. If read event data is missing (which can happen quite frequently) or not as expected, the item is suspect. Too many false negative suspect items become problematic to efficient authentication.

Read only tags also require no write time. Writable and re-writable tags typically need additional time to code data into tags, then verify the data received into the tag is correct. With read-only tags, data association of tags to database records occurs in a back-end system as the tags are applied to items. Read only RFID tags tend to have a smaller IC chip size, fewer transistor gates, less complexity, and ultimately less potential for malfunction.

As identified in the table below, there are four RFID carrier frequencies that are globally popular for passive RFID. Low frequency tags are not commonly deployed for low-cost tag applications. LF tags use turns of wire for their antennas making LF tags relatively expensive to produce and more bulky to laminate into disposable tag constructions such as labels. On the upper end of the radio spectrum, microwave frequencies of 2.45 GHz to 5.8 GHz are used extensively for active RFID systems, but historically have been largely underutilized for passive RFID systems until very recently. Passive microwave tags employ small antennas which lend them well to applications involving tagging of small items. The Hitachi  $\mu$ -chip is a read-only RFID technology that operates at 2.45GHz and is targeted at item-level RFID applications where tag data integrity is highly important and small, flexible, adaptable tag form factors are critical for success.

UHF tags are more commonly used for supply chain shipping labels or applications requiring passive tags with read distances of many meters. HF tags have much shorter read distances than UHF tags and can be found in applications such as laundry tracking and library books.

Primary Type	Frequency Range	Primary Frequency	Typical Application
Low Frequency (LF)	<300 KHz	125 KHz	<ul style="list-style-type: none"> <li>- Security Access</li> <li>- Auto Immobilization</li> <li>- Personal and ranch animal ID</li> <li>- WIP / asset tracking</li> <li>- Waste Management</li> </ul>
High Frequency (HF)	3 MHz to 30 MHz	13.56 MHz	<ul style="list-style-type: none"> <li>- Item Level Tracking</li> <li>- Library book ID</li> <li>- Clothing ID</li> </ul>
Ultra-High Frequency (UHF)	860 MHz to 950 MHz	915 MHz in US 950 MHz in Japan 868 MHz in Europe	<ul style="list-style-type: none"> <li>- Toll roads</li> <li>- Rail Car IDs</li> <li>- Case and pallet tracking</li> <li>- Item level tracking</li> </ul>
Microwave Frequency	2.45 GHz and 5.8 GHz	2.45 GHz	<ul style="list-style-type: none"> <li>- Toll collections</li> <li>- Real-time location systems (RTLS)</li> <li>- Authentication / anti-counterfeiting</li> <li>- Item level tracking</li> </ul>

LF and HF passive tags energize and communicate using induction coupling which employs coiled antenna types. Backscatter communication is generally used with UHF and microwave frequencies. These tags employ a dipole antenna of some type. Induction coupling is how rechargeable electric toothbrushes with no external power contacts recharge when returned to their electrified stands. Backscatter can be thought of as very

similar to a flashlight and a mirror. The RF energy of a reader (flashlight) is reflected by the tag (mirror). Within the reflected (backscattered) signal are tiny flutters (changes) that contain the tag's data. There are also many air interface communication protocols (the languages that tags and readers use to communicate back and forth) in both induction and backscatter communications.

To some degree, all tag frequencies are affected by nearby materials. The materials' dielectric property is the term used to describe how the material will alter, or detune RFID tag communication. In basic terms, water absorbs RF energy and metals reflect it. Therefore, tag placement on an item relative to the item's contents needs to be evaluated and in some cases, adapted and adjusted to compensate for the detuning or absorption effect as practical.

In summary, one RFID frequency and tag is not universally applicable to every kind of item containing every kind of substance for every kind of RFID tracking application. Different radio frequencies, communication methods, tag designs, and other criteria provide different readability characteristics. RFID convergence to one IC chip and one frequency and one communication technique is impossible. The key to RFID deployment success is to match price, read distance, tag form factors, reader hardware, back-end databases and networks, etc. to the most practical solution to match the right variety of RFID technology to solve the problem in an overall cost effective solution. A cost-effective solution may not be totally dependent on tag costs.

### ***Hitachi $\mu$ -chip Markets and Applications***

Development of the  $\mu$ -chip, Hitachi's first low-cost RFID tag, began in 1998 as a research project of Hitachi, Ltd.'s Central Research Laboratory as an authentication inclusion integrated circuit to help prevent counterfeit banknotes. As a result of the project, Hitachi identified numerous applications for this technology outside authenticating currency. Today's  $\mu$ -chip adoption runs the gambit from event admission tickets to loyalty cards to large scale automated manufacturing process control to product test sample tracking and many others. Generally,  $\mu$ -chip can assist in identity validation of any small, high risk, high value item.

$\mu$ -chip excels in business cases that can take advantage of its unique ID numbering structure. No two  $\mu$ -chips leave the factory with the same 26 character number. For larger applications, a  $\mu$ -chip UID header can be reserved specifically for a customer. The reserved header, which varies in length depending on expected tag volume, is commissioned exclusively for that customer and never recycled for any other application. "Run of the house" numbering is always available where no minimum volume requirements apply, and the same unique identifier scheme is maintained.

The fundamental concept of  $\mu$ -chip is to take as much of the cost and complexity and failure risk out of the RFID tags by emphasizing higher functionality in the reader, reader networks, and software. This concept allows for improvements in tag durability and disposability while improving the reader devices and read event capturing infrastructure at the same pace as other communication network infrastructure technology advances.

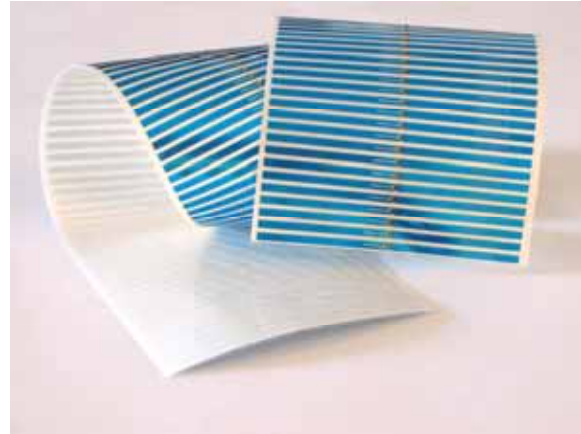
Each  $\mu$ -chip IC has a 128-bit unique identifier that is structurally part of the chip. Existing  $\mu$ -chip versions operate at 2.45 GHz, a frequency band that is universally available for use in all countries and typically does not require special radio operation licensing for the reader equipment which is both a radio transmitter and receiver. Usual communication speed for the data to transfer to the reader from the  $\mu$ -chip is 20

milliseconds. Maximum read distance between tag and reader antenna is 30 cm in free space. Depending on the object being tagged and its dielectric properties, read distance can change.

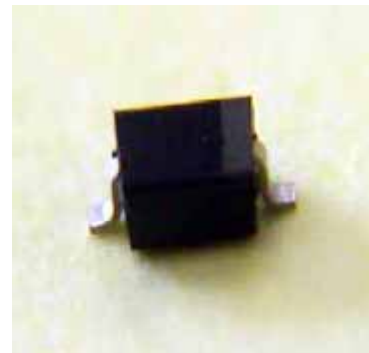
With a size of only 0.4 mm square, the production of chips per each silicon wafer is almost double that of typical 0.7mm square RFID chips. The COA (Chip on Aluminum) inlet is the base  $\mu$ -chip inlet used in most all tag designs. An inlet, also known as an inlay, is the basic RFID element within an RFID tag. An inlet is usually further fashioned into more protective specific-use tags such as labels. The  $\mu$ -chip COA inlet uses polyethylene naphthalate (PEN) film as the base substrate for the inlet. Ultrasound bonding technology is employed to connect the  $\mu$ -chip IC to the 52mm x 2mm printed etched mask aluminum antenna that is added to the top surface of the PEN film. The COA inlet packaging is small, thin, and flexible enough to permit the  $\mu$ -chip to be attached and embedded into a variety of small objects and can be easily embedded in paper or plastic card laminate constructions.

To further bring item level tagging to practical reality, the Ultra Small Resin Package  $\mu$ -chip inlet (URP) is a very small 1.7mm x 1.25mm ruggedized plastic packaging conforming to the same packaging characteristics of a discrete component diode. This  $\mu$ -chip inlet form factor was created specifically for mounting on printed circuit boards where the tag antenna is integrally printed on the circuit board and the URP mounted to the antenna via its two antenna terminal pins. The URP can also be attached to specialized antennas for highly customized tag applications. URP  $\mu$ -chips are used to authenticate and manage circuit boards for warranty service or returns validation.

RFID tags are less than half of the overall RFID solution equation. It takes tag reader devices and in larger deployments, reader management middleware to deliver read events from the tags into business applications where



Hitachi Mu-chip COA inlets in roll form. The  $\mu$ -chip IC chip is dark spot in center of the blue antenna strip. Inlet dimensions are 52mm x 2mm. The  $\mu$ -chip IC is 0.4mm sq.



Hitachi Mu-chip URP 1.7mm x 1.25mm package. A custom antenna is attached to the twin leads of the device. Picture is greatly enlarged to show detail.

the real value of RFID is generated. Depending on the deployment scale and characteristics, more powerful business applications are sometimes needed to manage and handle the granularity the RFID data brings. Hitachi America supports the North American markets with fully configuration-flexible fixed mount network device readers, handheld computer readers, and a few specialized reader modules for embedded systems and low power output reader cards for PDA devices. These reader devices, built on open standards and communication protocols, permit the crafting of adaptable, flexible  $\mu$ -chip applications.

Hitachi America's  $\mu$ -chip reader hardware is supported by a variety of sensor device middleware providers including Oracle Sensor Edge Server, GlobeRanger's iMotion platform, and IBM's Websphere as well as Hitachi America's own Java-based reader network management middleware which is offered ready-to-deploy in a Nitix (Linux for servers) operating system Web server.

The tests conducted with MDS Nordion suggest the  $\mu$ -chip COA packaging can be expected to survive more than 500 kilogray (kGy) of gamma ray exposure which translates to 20 or more gamma sterilization exposures. Few if any other low cost RFID tags can claim this degree of gamma durability.

### ***What is gamma radiation and how is it used?***

Gamma radiation is energy in the form of massless particles called photons, which are emitted during the process of radioactive decay. It falls within the same electromagnetic spectrum as visible light, ultraviolet and infrared, but has much higher energy. For gamma sterilization of single use medical devices, cobalt-60 is used exclusively as a radiation source. When gamma rays interact with material, the high energy photons (1.17 MeV and 1.33 MeV) knock electrons from orbit. These electrons, in turn, disrupt the molecular structure and DNA of living organisms. It is this principle of ionizing radiation that is employed for effectively reducing microorganisms on a wide variety of products, from medical devices to raw cosmetic ingredients to spices, meat and poultry. Table 1 lists some typical applications of gamma radiation, as well as the dose ranges associated with each application.

<b>Application</b>	<b>Dose Range (kGy)</b>
Disinfestation treatment of fruits and vegetables for export	0.1-0.5
Pathogen reduction in meat and poultry	1-3
Sanitation of spices	5-15
Sterilization of pharmaceuticals and cosmetic ingredients	5-15
Sterilization of medical devices	25-35
Materials modification	100+
Gem stone color enhancement	500+

Table 1: Gamma applications and dose ranges.

A typical gamma processing facility consists of a biological shield, a radiation source, a conveyor system and controls and safety systems. The biological shield is constructed of

thick, high-density concrete walls and provides a barrier to radiation. The radiation source is a series of Cobalt-60 'pencils' arranged in a planar array, which is stored in a deep pool of water inside the shield. Product to be sterilized is placed in large metal tote boxes, which are moved inside the shield by the conveyor mechanism. The radiation source is lifted out of the pool to expose the product, which is circulated around the source by the conveyor. Finished product is then moved out of the shield. A sophisticated control system manages the operation of the irradiator and robust safety interlocks are used to ensure that personnel cannot enter the irradiator when the source is in the unshielded position.

## ***The Gamma sterilization market***

There are approximately 160 large scale gamma irradiation facilities in operation globally. Of these, 120 were designed, built and installed by MDS Nordion, which also supplies 70% of the ongoing world market for Cobalt-60 gamma sources. Some irradiators are integrated into medical device manufacturing facilities, while others exist to provide contract sterilization services. Overall, more than 200 million cubic feet of medical devices are sterilized using gamma in the U.S. alone each year.

Commercial sterilization can be accomplished by means other than gamma rays including: steam (autoclaving), electron beam, dry heating, X-ray, and gas fumigation with ethylene oxide (EtO). Gamma sterilization is often preferred for products because of the fast turnaround and relatively low temperature of the process. Even frozen products can be sterilized with gamma. Moreover, it leaves no residue, unlike gas sterilization. Gamma sterilization is almost always performed when the product is in its final packaged form, and packaging material is not required to be gas-permeable, as is the case for EtO sterilization. Because of the high penetration of the gamma rays, products do not need to be packaged with any special geometry, and there are no restrictions on materials because of penetration. Both of these characteristics can present a challenge for e-beam sterilization.

The biggest limitation of gamma is material compatibility. Some products may become discolored, embrittled or emit an odd odor after being treated with gamma.

## ***The Apparent Antagonistic Forces Between RFID IC Chips and Gamma Energy***

Data storage in writable RFID tags is achieved by placing electrons in specific registers within the IC chip. Data is stored in binary form in the registers. A "1" is expressed by the presence of the electron in a given register and a "0" is expressed by the lack of an electron in a register. Gamma energy excites electrons causing them to move; and with enough excitement, the electrons can move out of their original register and into other registers or move entirely out of the chip itself. Enough gamma energy can damage the registers themselves, rendering the IC chip permanently damaged.

Some IC-based RFID tags claim to be gamma ray safe. These tags are more accurately gamma ray resistant to a specific kiloGray exposure threshold. The apparent immunity to

gamma damage is heavily dependent on encapsulation materials that allow specific RF signals to penetrate the encapsulation material, but restrict the penetration of gamma rays to a predictable level. The encapsulation material eventually succumbs to the gamma energy damage, rendering the tag unusable and the tag's data compromised.

The Hitachi  $\mu$ -chip tested by MDS Nordion was the bare COA inlet. This inlet has no encapsulation to shield it from the gamma ray exposure, because it does not require protection.

## ***Why Mu-chip is Not Adversely Affected by Gamma Energy***

Hitachi  $\mu$ -chip does not rely on data registers that store electrons. The lack of electron registers makes the  $\mu$ -chip data far less susceptible to alteration. The unique data identifier contained in each  $\mu$ -chip is structurally part of the chip itself. Much like how no two snowflakes are alike, no two  $\mu$ -chip ICs are identically hardcoded structurally with a unique identifier (UID).

Additionally, the method employed to create the  $\mu$ -chip IC and inlets create a very durable device. RFID label converting companies that form labels from bare inlets of various kinds of RFID technologies have commented on the remarkable durability of  $\mu$ -chip inlets. While many RFID inlets must be handled with great care during label processing to reduce damage from electrostatic discharge (ESD) and physical trauma of label making,  $\mu$ -chip inlet durability proves few tags damaged in the label making process.

## ***The $\mu$ -chip Gamma Ray Tests and Results***

A disposable surgical device manufacturer evaluating RFID for its products exposed a sample population of 30  $\mu$ -chip inlays to 50 kGy during its RFID investigation for item-level tagging. All 30  $\mu$ -chip labels survived the 50 kGy exposure. No other RFID tag that the manufacturer tried came close to this 100% survival rate. MDS Nordion, a leader in the gamma sterilization industry, had been investigating the radiation resistance of various RFID tags in order to make recommendations to customers. As a result of the initial discovery by the device manufacturer, Hitachi and MDS Nordion initiated a number of gamma exposure tests to bare  $\mu$ -chip inlets to see how extreme  $\mu$ -chip's apparent strength against gamma rays truly was.

All tests were conducted with the  $\mu$ -chip COA inlet. COA is the most commonly used  $\mu$ -chip inlet as it is a good compromise between price, performance, and ease to attach and encapsulate into items, especially medical and surgical disposables and the packaging these items are shipped in. The COA inlets used for testing were wet inlets, meaning the back side of the PEN film of the inlet has an added layer of acrylic pressure sensitive adhesive common to the pharmaceutical labeling industry. The adhesive is protected by a paper release liner. During wet inlet production excess PEN material around the inlet antenna is die cut and stripped away from the release liner yielding a continuous ribbon of singular, detached inlets that can be dispensed as-is into items that will offer added physical protection or further converted into more complex label constructions.

MDS Nordion exposed a sample of 30  $\mu$ -chip COA inlets to 100 kGy and 7 additional COA inlets to 200 kGy. The test team expected to see some fallout in read reliability on these inlets. However, all tags were fully readable after exposure. A second set of 30 inlets were exposed to 200 kGy and 5 inlets were exposed to 500 kGy. All these test inlets survived as well. Finally, MDS Nordion exposed 30 inlets to 500 kGy. Again, all inlets responded to the reader with their UIDs and with no detectable readability damage. Tags were exposed in both a GammaCell 220 self-contained irradiator at MDS Nordion's facility in Ottawa, and at the Canadian Irradiation Centre, a testing, research and training center in Laval, Quebec.

To the right are three of the test subject wet inlets that were subjected to the 500 kGy exposure. As expected, the paper release liner shows signs of severe accelerated age. The paper release liner of the high

gamma dose inlets crumbled upon touch. The acrylic adhesive lost some of its holding power. It is important to note, that had these inlets been attached to an item prior to the gamma exposure, the inlets would likely have remained well affixed to the item as the adhesive was much less compromised than the paper release liner. The aluminum antenna strips and the  $\mu$ -chip IC chip appeared to be neither physically nor functionally affected.



Three Hitachi Mu-chip COA wet inlets after 500 kGy gamma exposure. Note the severe degradation of the paper release liner. Inlet readability was not affected by the irradiation. Photo enlarged to show detail.

### ***Practical Applications for $\mu$ -chip's Gamma Safe Characteristics***

Gamma survivability aside, Hitachi  $\mu$ -chip is best suited as a highly durable license plate RFID tag to facilitate positive identification of high value items. Positive identification can be further broken down into three primary use cases:

*Authentication*—verifying the item is not false or imitation.

Authentication applications apply to items such as currency, gaming tokens, event ticketing, collectables and fine art, critical system parts, DVDs, loyalty/membership cards, pharmaceuticals. Disposable medical and surgical items where there is risk or concern the item may not be authentic factory item fall under this use case.

*Traceability*—validating of the item's history.

Traceability use cases can apply to life sciences/medical specimens, legal documents, product diversion (grey market goods). Often times, medical and surgical items are diverted from their original markets.  $\mu$ -chip can help trace the source of the product diversion.

*Work-in-Process (WIP)*—managing and controlling manufacturing process.

Work flow control, production yield management, R&D process validation and analysis all fall under WIP. WIP applications are sometimes described as “four walls” closed loop applications because the purpose of the RFID tag is to facilitate a process that is contained to one or few locations. WIP RFID applies to the item produced as well as the tools and parts utilized in the production process. Often times, containers, delivery tubes, and other utensils are routinely gamma sterilized in food or pharmaceutical product production.  $\mu$ -chip can be integral to process validation protocols that involve gamma sterilization of key manufacturing tools. The maximum gamma ray exposure used in the tests described in this white paper was 500 kGy. The actual survivability of  $\mu$ -chip to gamma rays actually may be much, much higher.  $\mu$ -chip may provide an ideal identity device for trays, racks, and many other carrier devices used inside gamma ray sterilization equipment.

To summarize,  $\mu$ -chip is ideally suited to RFID use cases that demand:

- Highly reliable tag quality (bad tags in the system cause problems)
- License plate-type tag data preferred
- Small tag footprint
- Authentication or anti-counterfeiting (IDs not easily duplicated)
- Large individual item populations needing tags
- Short read distances (12” or less) preferred
- Closed to extended loop applications

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March 25, 2008