

# Development of Traceability Management System Using IC Tag

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In recent years, quality control has become more and more essential, and the importance of product traceability has been growing for use in manufacturing, inspection and circulation records. Therefore, IHI has developed a traceability management system using IC tags, and the system is expected to be widely used in the future. The system comprises a process inspection management system, which manages inspection records of each production process, and a circulation record management system, which manages the circulation records after shipping. This system is applied to the production and distribution of medical equipment. This paper outlines the features of these systems.

## 1. Introduction

Recently, consumers more strictly check the safety of food, and the traceability of food's processing and distribution history is drawing more attention. Against such a background, the traceability management system for food is gradually being utilized. For industrial products as well, stricter quality control is required, and proper management of production, inspection and distribution histories is sought. From the viewpoints of improving reliability, maintaining brand value, and disclosing information to customers, product traceability is increasingly important.

The inspection history of products has until now been recorded on paper by inspectors, but to ensure quality control, including prevention of data falsification and uniform management of inspection records, computerization is increasingly required.

We have, therefore, developed a traceability management system comprising a process inspection

management system to control the inspection records of processes in production and a distribution history management system to control the distribution history after products are shipped, using IC tags.

This paper outlines the system and its main features.

## 2. Features of IC Tag

The IC tag, also called RFID (Radio Frequency ID), is a tag equipped with a chip that can read and write data through radio communication. Recently, with decreasing unit prices, progress of work standardization in various industries, and Revision of the Radio Law, it has been used in various fields.

**Table 1** shows a comparison between the IC tag and other recording devices. The IC tag has such features as ① large storage capacity, ② capability of rewriting data, and ③ capability of recognizing an invisible place. But it is necessary to select a proper IC tag in accordance with the application when a system is constructed because its characteristic change depending

**Table 1** RFID ( IC tag ) compared with other recording devices

Item	Paper sheet	Bar code	Two-dimensional code	IC tag
Easy uniform management of data	△	◎	◎	◎
Size of storage capacity	◎	×	○	○
Writable or not	○	×	×	○
Data reliability (occurrence of entry mistake)	×	◎	◎	◎
Dust-resistant (resistance against contamination/dust)	△	×	△	○
Effect of shielding materials (recognition of invisible place)	×	×	×	○

(Note) ◎ : Superior  
 ○ : Possible/suitable  
 △ : Problem  
 × : Impossible/not suitable

on the communication system, communication frequency, and chip type/shape.

IHI has already utilized IC tags for asset management at its factories, security control of containers, and article control with distribution systems, and accumulated IC tag technology. This time IHI has developed a system for managing product traceability by exploiting its past knowledge and experience in IC tag utilization while also considering the system's future extendability.

### 3. Traceability management system

#### 3.1 Outline

The traceability management system comprises a process inspection management system for factory use and a distribution history management system to control the distribution history after shipping. **Figure 1** shows the general system flow diagram of the traceability management system.

With the process inspection management system inspection results are recorded in the database (DB) and the IC tags are attached to semi-processed products in such processes as assembly, operation, completion, and storage by a worker using a portable information terminal (PDA: Personal Digital Assistant) equipped with an IC tag reader/writer. The inspection conditions of semi-processed products and shipping conditions of products can be referred to through other terminals connected to the intranet.

With the distribution history management system, on the other hand, the IC tag showing the manufacturing No. to identify each product is attached to the product, and the agency reads the manufacturing No. of the IC tag with a PDA when receiving/shipping the products and writes the receiving/shipping records from the

internet web site for controlling the distribution history. This makes it possible to control the distribution history from shipping to delivery to the final customer through the agency.

#### 3.2 System configuration

**Figure 2** shows the configuration of this system.

The process inspection management system comprises a database server to store data, an IC tag for worker, an IC tag for apparatus, a PDA to enter the inspection results, a PC for inspection/shipping work and an intranet to connect them.

The distribution history management system comprises a database server to store data, a Web server to provide distribution history information to the internet, an IC tag for product, a PDA to register warehousing/shipping records at agencies, etc. and network equipment. This realizes continuous history management from production history to distribution history.

#### 3.3 Features

The main features of this system are shown below.

##### 3.3.1 Double registering of data

With the process inspection management system, the inspection results in the production processes are registered in the database and also in the IC tags attached to semi-processed products.

Registering the inspection results in the IC tag attached to the semi-processed product realizes paperless inspection and also makes it possible to easily check at the site the conditions of the semi-processed product by just reading the attached IC tag, even at a place without a wired/wireless LAN environment within the factory. Since the next work content is displayed on the PDA on the basis of the information

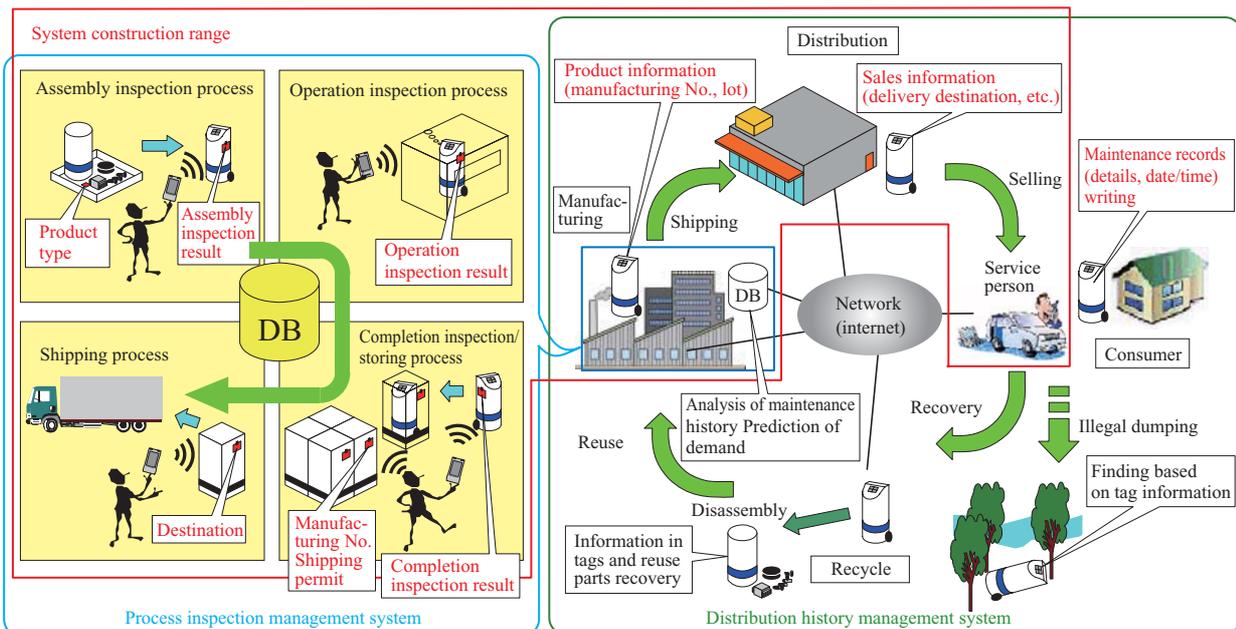


Fig. 1 General system flow diagram

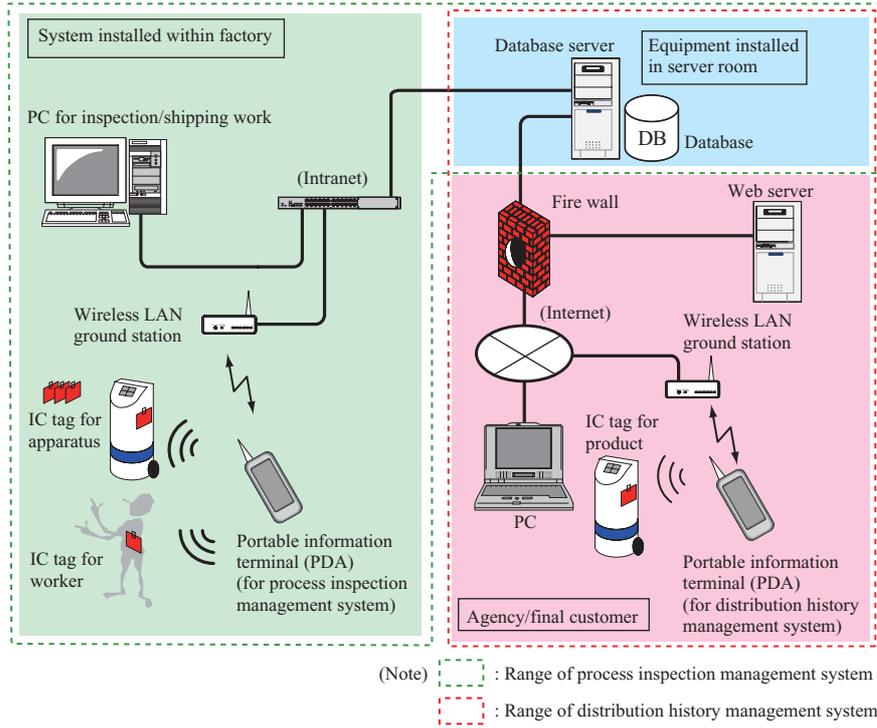


Fig. 2 System configuration

recorded on the IC tag, it is possible to prevent the inspection work at the site from going back.

On the other hand, by registering the inspection results in the database, the person in charge of production management can check in realtime the progress of semi-processed products on the list screen of inspection results shown in Fig. 3. It is also possible to check the details of the inspection record for each semi-processed product as shown in Fig. 4. Since it is equipped with a function to print out the inspection record, the inspection record sheet of paper can be obtained when required. Furthermore, by recording the inspection results in the database in a unified way, it is possible to collect data for analysis useful for investigating measures for higher efficiency of work, including grasping of trouble tendency and work time of each process.

**3.3.2 Easy adding/changing of inspection items**

On the manufacturing line, new products are often added, processes are frequently reviewed and inspection items are added or changed lots of times. The site manager must be able to handle these cases alone. The process inspection management system, therefore, is provided with functions to add/change inspection items so that products, processes, and inspection items can be automatically added/changed just by preparing anew the inspection sheet data in accordance with the specified format. Figure 5 shows an image of adding/changing the inspection details.

**3.3.3 Usability of PDA**

A PDA is convenient to carry, but its use is limited because the screen is small and operation buttons are

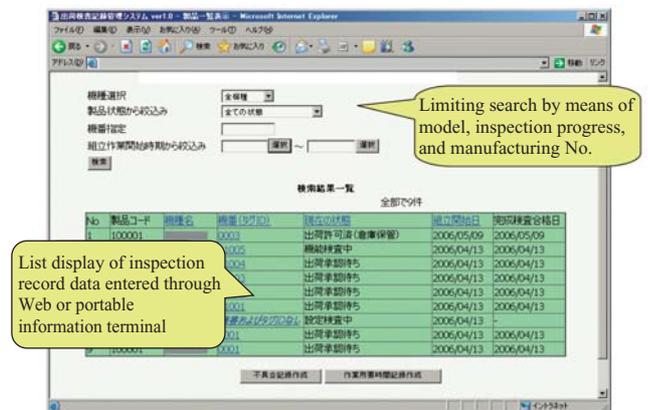


Fig. 3 List of inspection results ( image on website display )

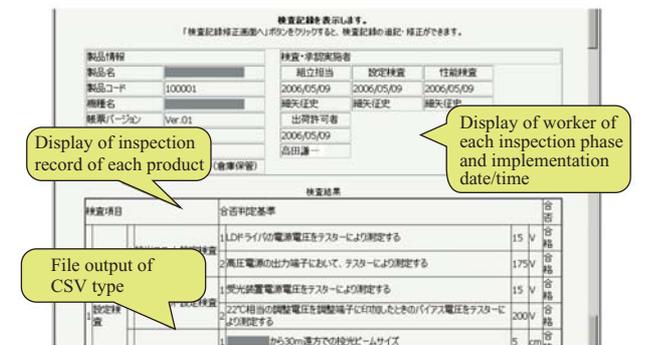


Fig. 4 Product inspection records ( image on website display )

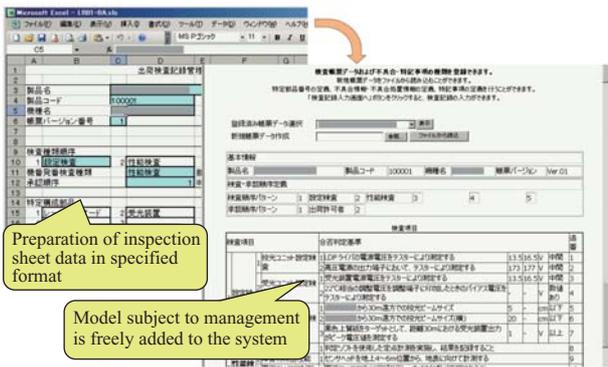


Fig. 5 Addition or change of inspection items

limited. For the inspection results, it is necessary to include not only OK/NG judgment but also reasons when a value is entered or when trouble has occurred. Many workers at the site are not used to PDAs, and improving their usability is a key to their smooth introduction.

As Fig. 6 shows, therefore, we adopted the operation method of mobile phone with which many people are familiar so as to facilitate such operations as moving the screen and registering/defining data centering on the keys arranged in a crisscross fashion at the center of the PDA.

For recording reasons for rejection and comments, we adopted a system that allows selection from a list of possible reasons and comments registered in advance. This shortens the data entering time at the site.

3.3.4 Reuse of IC tags

The information recorded in the IC tags for inspection management utilized with the process inspection management system is no more required after shipping. The IC tags for inspection management require larger storage capacity to record inspection results, but the IC tags for distribution history management are relatively small in data volume to be recorded, and in many cases, they cannot be recovered.

We, therefore, adopted a type of IC tags for process inspection management system that can be removed

before packaging after products are completed and initialized for reuse. Since the IC tags are reused within the factory, they have cost merits. For the distribution history management system, different, less-expensive IC tags are used and attached to products when shipping.

3.3.5 Coping with unspecified number of distribution history

While it is almost always possible to specify the production history of semi-processed products within the factory, it is often impossible to specify distribution routes to final customers for the products after they are shipped. For this reason, we improved the database structure for the distribution history management system and did not limit the number of distribution histories in order to cope with unspecified numbers of agencies in distribution. This makes it possible to record the maintenance after delivery of products, control in uniformed way the entire product life cycle, including disposal and recovery, and cope with future extensions.

3.3.6 Information security

Some assembly processing, and inspection of parts and products can be done only by workers with particular qualification and knowledge. To ensure quality control, a management system must be able to confirm that this kind of work is done only by qualified workers.

With the process inspection management system, therefore, workers are registered in advance for each process and other workers are verified by reading their IC tags before work begins. The traceability information of agencies and final customers can only be referred to by those who purchased/sold the products themselves, thus assuring information security.

4. Application to medical equipment

For medical equipment, the management of the inspection records of production processes has been made mandatory by the Pharmaceutical Affairs Law. And a revision of the Pharmaceutical Affairs Law in April 2005, required the management of distribution history of medical equipment after shipping. In the future, it is considered that the traceability including maintenance and disposal will increasingly be required.

Ishikawajima-Shibaura Machinery Co., Ltd. (presently IHI Shibaura Machinery Corporation), which manufactures medical equipment, introduced a traceability management system into the production processes of products approved by the Pharmaceutical Affairs Law and started its operation in fiscal 2005. It has already been introduced for some models, and thanks to its inspection sheet function, the operation is smoothly done by the workers alone.

When this system was introduced, a function to link it with the existing order receiving/issuing system was added, making it possible to confirm by way of electronic data that products subject to shipping passed all the inspections.

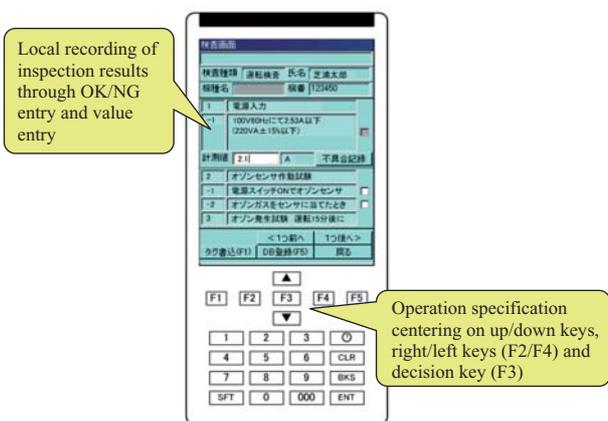


Fig 6 Entry image of inspection results with a PDA

Inspection history details are now stored in the database, making it possible to more quickly respond to inquiries from customers compared with the conventional paper inspection sheets. By analyzing inspection result data stored in the database and the actual data of the site including required work time for each process, we can expect ripple effects to improve production management in the future. We can also expect the better services for our customers including the possibility of planning detailed maintenance for each customer based on the distribution history.

## 5. Conclusion

From the viewpoint of higher efficiency of production at the factory, “Mieruka” (identifying problems and bringing them to the foreground) of production processes has long been called for. From the viewpoint of winning CS (Customer Satisfaction), traceability management after shipping is increasingly important. To meet this need, IHI has developed the traceability

management system comprising a process inspection management system and distribution history management system and applied it for traceability management of medical equipment.

In the future, we will promote the expanded application of this system to improve quality control and productivity at various factories. We will also promote extension of the history management range to maintenance after delivery to final customers and disposal/recovery.

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