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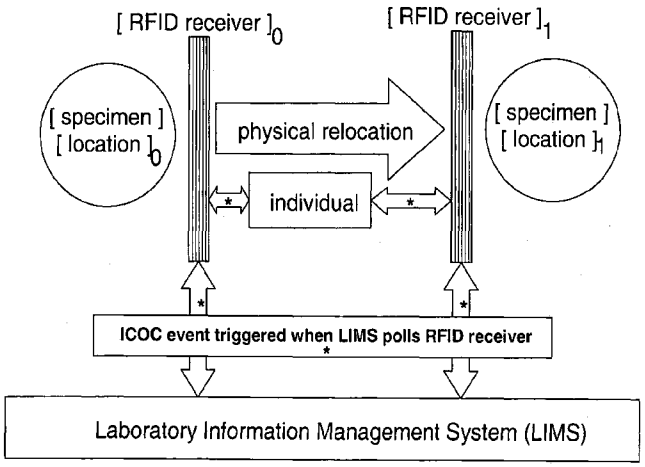
(54) **Title:** LABORATORY INFORMATION MANAGEMENT USING RADIO FREQUENCY IDENTIFICATION



(57) **Abstract:** The present invention is a method for use by a plurality of users to manage and document activities within a laboratory environment using radio frequency identification (RFID) tags as automated data-entry devices within a Laboratory Information Management System (LEMS). Standard or custom RFID tags are attached to any number or type of desired objects, including but not limited to samples or specimens; laboratory instruments; laboratory reagents; laboratory expendable supplies; and storage areas (including freezers, refrigerators, incubators, etc.). Laboratory workers also wear identification badges incorporating RFID tags. Any laboratory activity can be monitored and automatically documented in this manner.

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LABORATORY INFORMATION MANAGEMENT USING RADIO FREQUENCY IDENTIFICATION

PRIORITY CLAIM

Pursuant to 35 U.S.C. § 119(e), applicants claim the benefit of the filing date of provisional patent application number 60/839,808 having filing date of August 24, 2006.

BACKGROUND AND SUMMARY OF INVENTION

The present invention relates generally to the effective and efficient management of intra-laboratory activities by using RFID tags within a LIMS, across a plurality of users, a plurality of objects, and a plurality of intra-laboratory locations.

Commercial, academic, medical and forensic laboratories have a need to track, monitor, and manage the activities associated with samples and specimens. A primary consideration is the custody of said samples and specimens, as well as any potential changes which may occur to an individual specimen or sample. Managing a laboratory requires managing thousands of specimens or samples; hundreds of potential changes may occur to any individual specimen or sample.

Current state-of-the-art is to track laboratory activities in a labor-intensive manual tracking system. For example, when a technician removes a specimen from storage, a signature (physical or digital) is required. This may be done via pen-and-paper; it may be done by scanning a barcode; it may be done by completing a prompt in a LIMS. Each of these manual actions is inefficient, and prone to human oversight errors. In a circumstance where verifiable chain-of-custody could be a critical issue in the development of a new drug, or in the integrity of forensic evidence, these human errors can have great financial, ethical, or regulatory implications.

In a regulated laboratory environment, like those involved in drug development, or forensic chemistry, or even environmental testing, the preserve-the-chain-of-custody concept generally is extended to any component of a laboratory test, project, or study.

Properly and appropriately tracking all of the components of a complex, multiple-year, multiple-location clinical trial, for instance may create millions of data points. Each of those data points in a manual tracking system is subject to error, decreasing the value of the study, and ultimately increasing the risk associated with the use of the datum. Managing data of this level of importance, and of this magnitude, is the reason behind the development of a LIMS as a concept.

However, even a state-of-the-art LIMS is prone to manual errors whenever the entry of the data occurs only via human interaction. The most common error in these settings is oversight. When the manual entry system is cumbersome, tedious, or slow, an opportunity for oversight error exists.

RFID tags, LIMS and various manual tracking systems are known in the art. However, prior art does not integrate the use of RFID tag technologies into current LIMS software. This invention provides a mechanism for laboratory management to minimize the risk associated with manual tracking systems by using RFID tags as data-entry devices within existing LIMS software. The present invention enables laboratory management to monitor the custody of any given specimen or sample; to monitor the movement of specimens, samples, or any other laboratory device or expendable through the laboratory; to document which employee moved a given specimen, or used a given reagent; to demonstrate that specimens or waste have been disposed properly; and to associate such events with particular laboratory tests, projects, or studies by the use of RFID tags.

To accomplish the present invention, the following steps were employed:
1. a relational database was developed within a LIMS. The database structure includes information about a given object, and how it is analyzed within a project or study, including all components of said project or study.

2. RFID tags were applied to various objects such as specimens, laboratory devices, laboratory expendables, and employee identity badges.

3. RFID antennae (receivers) were positioned around the doorways of refrigerators, freezers, and specific laboratory areas. RFID receivers were also positioned around waste

disposal containers; on laboratory bench tops; and handheld wireless RFID receivers were also employed.

4. Any change in any object tagged with an RFID tag can then detected or recorded automatically, by use of the RFID receiver. The receiver is integrated into a LIMS by the current invention, and a unique data point is created which corresponds to a change in a tagged object.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1 through 7 illustrate the structure, logic and components of the present invention, according to one embodiment of the invention, which is a system for documenting laboratory activity via RFID tags and incorporating the data within a LIMS. Note that this is not the only embodiment of the invention; other, different embodiments of this invention may be made without departing from the spirit of the invention.

Figure 1 illustrates the general conceptual structure and relationship of the invention components and their relationship to the RFID tags and the LIMS.

Figure 2 represents how an action on an object by an individual changes the object within the context of this invention.

Figure 3 represents an action on an object by an individual creates an Internal Chain of Custody ("ICOC") event within the context of this invention.

Figure 4 represents how an ICOC event is captured in the LIMS by means of manual recording.

Figure 5 represents the RFID-based capture of ICOC events.

Figure 6 represents how RFID transmitters and receivers are used to track physical relocation of objects and to record that data in the LIMS.

Figure 7 represents how an ICOC event is triggered when the LIMS polls an RFID receiver.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 represents a conceptual overview of the structure and relationship between objects that may be tagged with RFID transmitters and/or receivers and the LIMS. Any desired number or type of objects may be tagged or identified for incorporation into the RFID-LIMS combination. As depicted in Figures 1 and 2, an "object" can be:

1) a sample or specimen, or a sample (or specimen)-related item, such as:

   a) Aliquot
   b) Sub-sample
   c) Extract
   d) Dilution of extract
   e) Derivatized or otherwise prepared for analysis
   f) Sample vial "as analyzed"
   g) Retained sample or specimen
   h) Fortified sample
   i) Fortified extract

Each such sample- or specimen-related item is identified with a distinct RFID tag.

or, an "object" may be:

2) a laboratory supply or laboratory expendable, such as:

   a) Reagent
   b) Sample preparation device (e.g., solid phase extraction [SPE] device)
   c) Laboratory-prepared solutions
   d) Laboratory container (tube, vial, well-plate)
   e) Dispensing device
   f) Safety equipment (e.g., latex gloves, flammable spill clean-up kit)
   g) Measuring devices (e.g., pipettes, syringes)
   h) Chromatography columns (e.g., LC, GC, IC)

Each such laboratory supply or expendable is identified with a distinct RFID tag.

or, an "object" may be:

3) a laboratory device or instrument, or associated with a laboratory device or instrument, such as:

   a) Analytical instrument (e.g., GC, GC-MS, HPLC, ICP-MS, LC/MS/MS)
   b) Preparation instrument (e.g., mill, chopper)
   c) Analytical balance

Each such laboratory device or instrument is identified with a distinct RFID tag.

or, an "object" may be:

4) a collection of items, such as:

a) Collection of sample extract vials (e.g., 100 HPLC autosampler vials)
b) Collection of primary or secondary standards

Each such collection of items is identified with a distinct RFID tag.

or, an "object" may be:

5) a reference or comparison material, such as:

a) Primary reference standard
b) Secondary reference standard
c) Mixed reference standard
d) Fortification standard solution
e) Laboratory reference material
f) Laboratory control material
g) Reagent control or blank

Each such reference material or related item is identified with a distinct RFID tag.

or, an "object" may be:

6) a laboratory waste / disposal collection container, or associated with such containers, such as:

a) Waste solvent drums
b) Trash cans or barrels
c) Glass collection drums
d) Quarantined items intended to be disposed

Each such waste collection container is identified with a distinct RFID tag.

or, an "object" may be:

7) a monitored area, room, compartment, chamber, container, or other enclosed area, such as:

a) room
b) freezer
c) refrigerator
d) incubator
e) any temperature-controlled storage area
f) building or facility doorways or gates through which sample custody flow occurs
g) waste container

or, an "object" may be:

8) an individual, such as an employee generally, an employee specifically authorized to perform specific tasks, a robotic device, or a visitor within a laboratory or other facility.

As described in Figure 2, an action on an object (as defined above) by an individual changes the object. An "action" is any change in any object created by any individual, including:

1) change in location
2) change in mass or weight or chemical composition
3) use or utilization in a particular test, project, or study
4) a change in temperature, humidity or other environmental condition which may be monitored

An "individual" may be:
1) an employee
2) a consultant
3) a contract service person
4) any individual creating a change in any object
5) a robotic device

Figure 3 graphically represents that an "ICOC event" ("Internal Chain of Custody event") occurs whenever an object is changed by the action of an individual. As further depicted in Figure 4, ICOC events may be captured in the LIMS by manual recording of the event and associated data entry into the LIMS database structure. However, manual recording of data is prone to errors and is not as accurate as RFID-based capture of ICOC events. This invention improves current practice and reduces recording errors by using RFID-based capturing of ICOC events,

As depicted in Figure 5, ICOC events are "captured" (i.e., become data points in the relational database of a LIMS) when an object bearing an RFID tag is interrogated by an RFID receiver at the entrance of an object which is a monitored area, room, compartment, chamber, container, or other enclosed area, such as a room; a freezer; a refrigerator; an incubator; any temperature-controlled storage area; a waste container; or a building or facility entrance, doorway, portal or gate through which sample custody flow occurs.

In the current invention, it is this interaction between RFID tags associated with objects and individuals; RFID receivers strategically located within a laboratory facility; and a LIMS which enables the efficient and effective automated management of laboratory activities, including sample or specimen custody.

Figure 6 illustrates a specific example of the current invention in which an RFID-tagged specimen is physically moved from one location to a new location, and where each location possesses an RFID-receiver connected to a LIMS.

Definitions of "object" and "individual" are as above. The physical relocation in this example is an "action".

In this example, both the specimen and the location are "objects". The location-as-object is communicated to the LIMS through an RFID-receiver. An RFID-receiver-antenna is placed around the doorway to a location. When an individual enters location 0, the LIMS records that entrance. When said individual removes a specimen from location 0, the LIMS records that removal. No other activity is required by the individual. Moving the specimen through the doorway triggers the change in status.

This change in status is a recordable ICOC event, and is automatically recorded in the LIMS.

The individual moves the specimen from one location to another. Upon entering a second location ("location 1" in this example), the specimen and the individual both pass through a second RF field generated by a second RFID-receiver-antenna. This action creates a new data point in the LIMS, indicating that the specimen is now in location 1, and that the relocation was conducted by the individual. Again, no other documentation is required by the individual. The RFID antenna detects both the specimen RFID tag and the individual's RFID badge, both at the entrance to location 0, and the entrance to location 1.

Note also that the invention can be structured to control access to any object. For example, an access to "object" (i.e., a controlled substance freezer) is controlled from within the LIMS using an electronic lock. An RFID-receiver detects the RFID employee-badge-tag; determines whether the employee is permitted access to the freezer, and prompts (on-screen) the employee to verify that he or she wishes to enter the controlled space. On "yes", the door is unlocked. ICOC events occur when: 1) the badge is detected; 2) when there is a positive response to the prompt; 3) when tagged objects leave the freezer; and 4) then the door is relocked.

Figure 7 graphically illustrates how the LIMS and RFID systems interact. As described above, the invention comprises an object (i.e., a specimen, a sample, an individual, a container, a location, etc.) to which an RFID tag is attached or applied in some mechanical fashion; an RFID antenna within proximity to a controlled or secured location; an RFID receiver which is capable of interrogating the RFID tag in combination with the antenna, and which contains a storage device capable of storing data received from the RFID tag; and a LIMS which includes a relational database in which both the RFID tag data and the RFID receiver data can be stored.

In a simple example, movement of specimens in and out of a controlled temperature storage compartment such as a freezer is to be monitored. In close proximity to the freezer door, an RFID antenna and accompanying RFID receiver is positioned.

At time intervals which are variables to be managed using software contained within a LIMS, the RFID receiver interrogates the RFID chip (a storage device retaining the unique identity of the device). The data acquired from this interrogation is stored within the buffer of the RFID receiver.

Similarly, when the movement of an RFID-labeled device is detected by the RFID receiver by the movement of an RFID tag into, out of, or through the RF field emanating from the RFID receiver, the identity data (including specimen ID, location ID, and individual ID) are downloaded to, and stored within the buffer of the RFID receiver.

At time intervals which are variables to be managed using software contained within a LIMS, the LIMS "polls" the buffer of the RFID receiver and downloads any newly acquired data into the relational database of the LIMS. This polling can be accomplished either through a hardwired or wireless connection.

Each polling of the RFID receiver buffer can create an ICOC event if, during the interval between pollings, movement of an RFID device has been detected by the RFID receiver.

CLAIMS

We claim:

1. A method to manage and document activities in a laboratory environment using radio frequency identification within a laboratory information management system comprising the steps of:

developing a relational database within a laboratory management information system to manage information concerning action on at least one object within the laboratory;

applying at least one radio frequency identification tag to the object;

positioning a plurality of radio frequency identification receivers at selected locations within the laboratory to detect action on the tagged object; and

integrating the radio frequency identification receivers to the laboratory information management system to record action on the tagged object in the relational database.

2. The method specified in claim 1, wherein the object is a sample, specimen, container, device, instrument, reference material, chamber, compartment, room, laboratory area, or person.

3. The method specified in claim 1, wherein the action is any change in any object created by an individual.

4. The method specified in claim 1, wherein the action is any change in location, mass, weight, chemical composition, physical state, or monitored environmental condition of the object.

5. The method specified in claim 3, wherein the individual is a natural person or robotic device.

6. The method specified in claim 1, wherein the radio frequency receivers are placed at the entrance to a building, room, compartment, chamber, container, temperature-controlled storage area, or waste container in the laboratory.

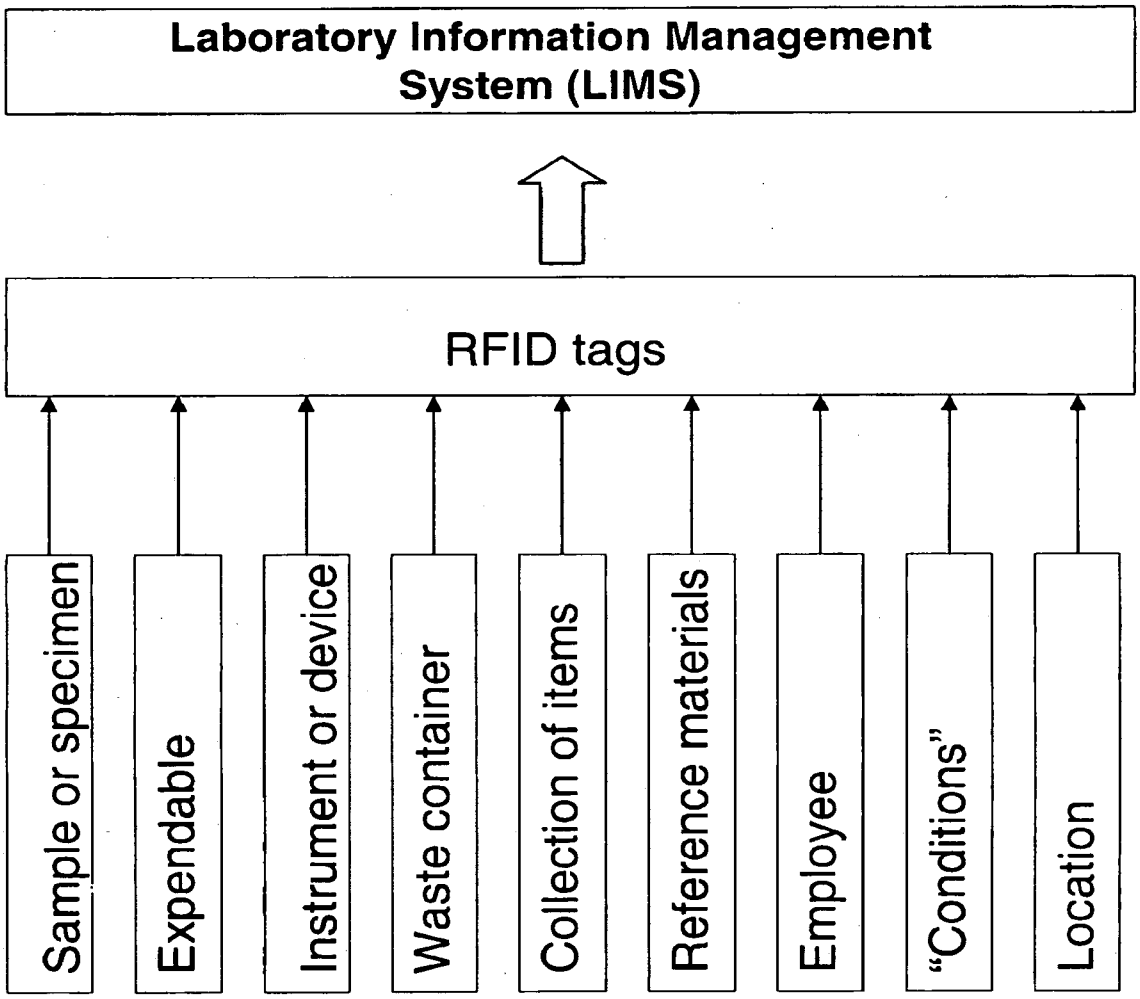
7. The method specified in claim 1, wherein the radio frequency receivers store, in the memory of the receivers, information about an action on a tagged object.

8. The method specified in claim 1, wherein the integration of radio frequency identification receivers to the laboratory information system is accomplished either through a hardwired or wireless connection.

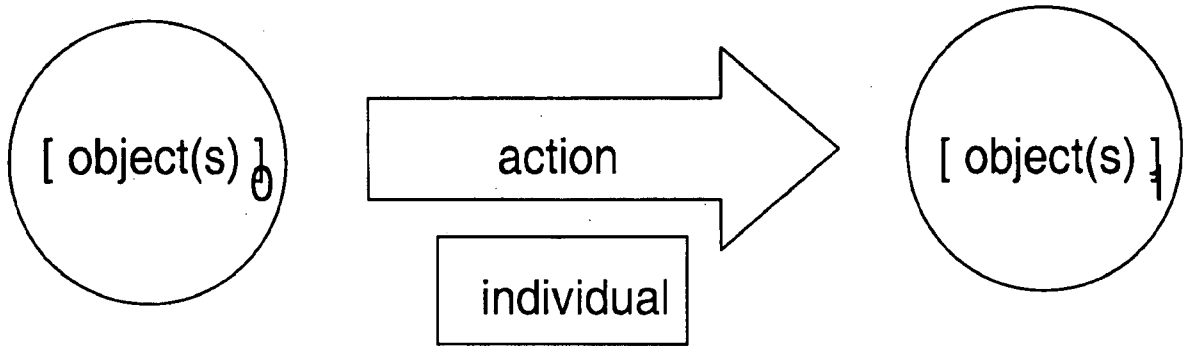
9. The method specified in claim 1, wherein the radio frequency identification receivers receive and store information until polled by the laboratory management system.

10. A method to manage and document activities in a laboratory environment using radio frequency identification within a laboratory information management system comprising the steps of developing a relational database within a laboratory management information system to manage information concerning action on at least one object within the laboratory, wherein the object is a sample, specimen, container, device, instrument, reference material, chamber, compartment, room, laboratory area, or person and wherein the action is any change in any object created by an individual; applying at least one radio frequency identification tag to the object; positioning a plurality of radio frequency identification receivers at selected locations within the laboratory to detect action on the tagged object; and integrating the radio frequency identification receivers to the laboratory information management system to record action on the tagged object in the relational database.

Lloyd, Laboratory Information Management Using Radio Frequency identification Atty Dkt. 2549-1804



An <u>action</u> on an <u>object</u> by an <u>individual</u> changes the object



Laboratory Information Management System (LIMS)

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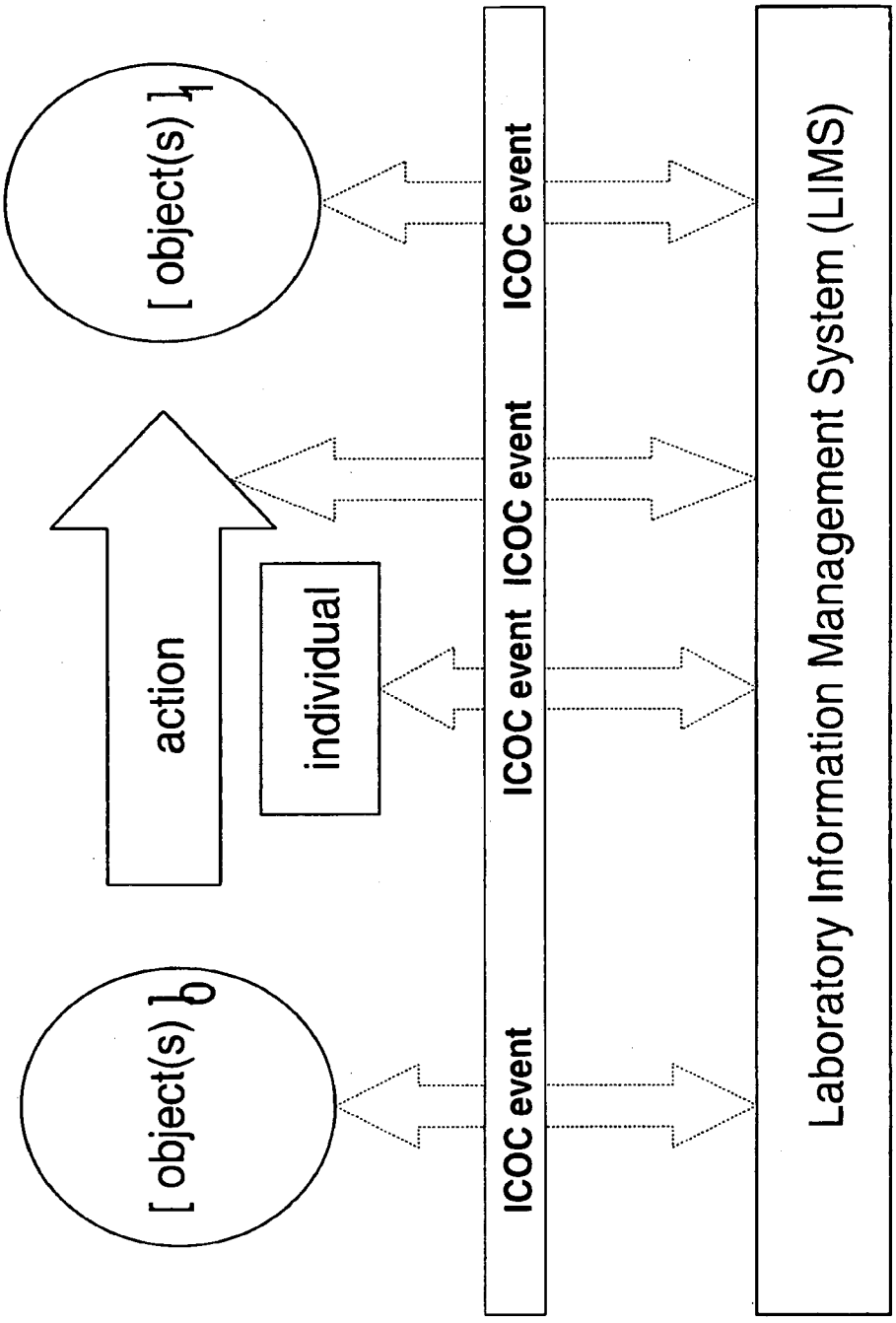
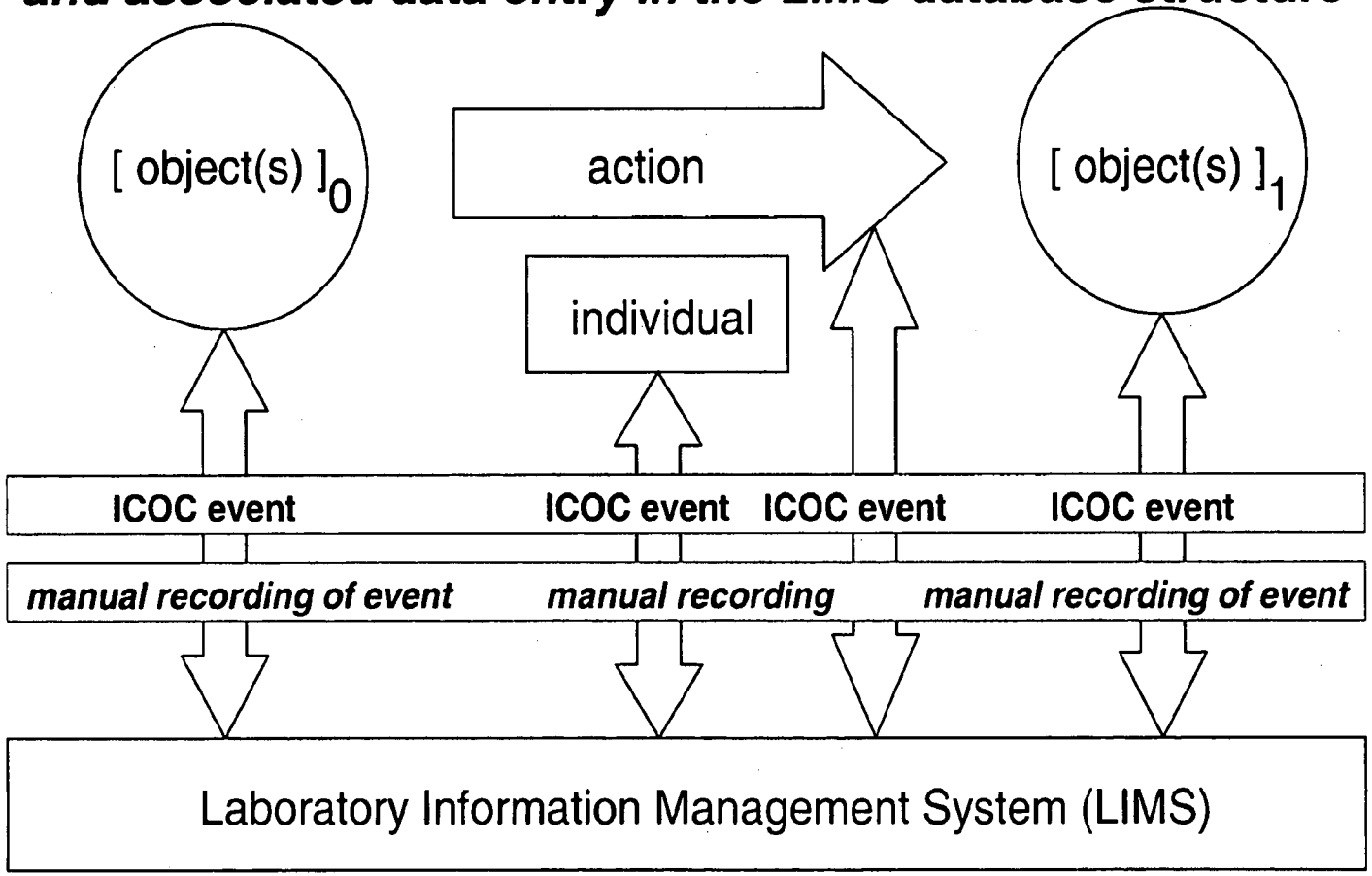
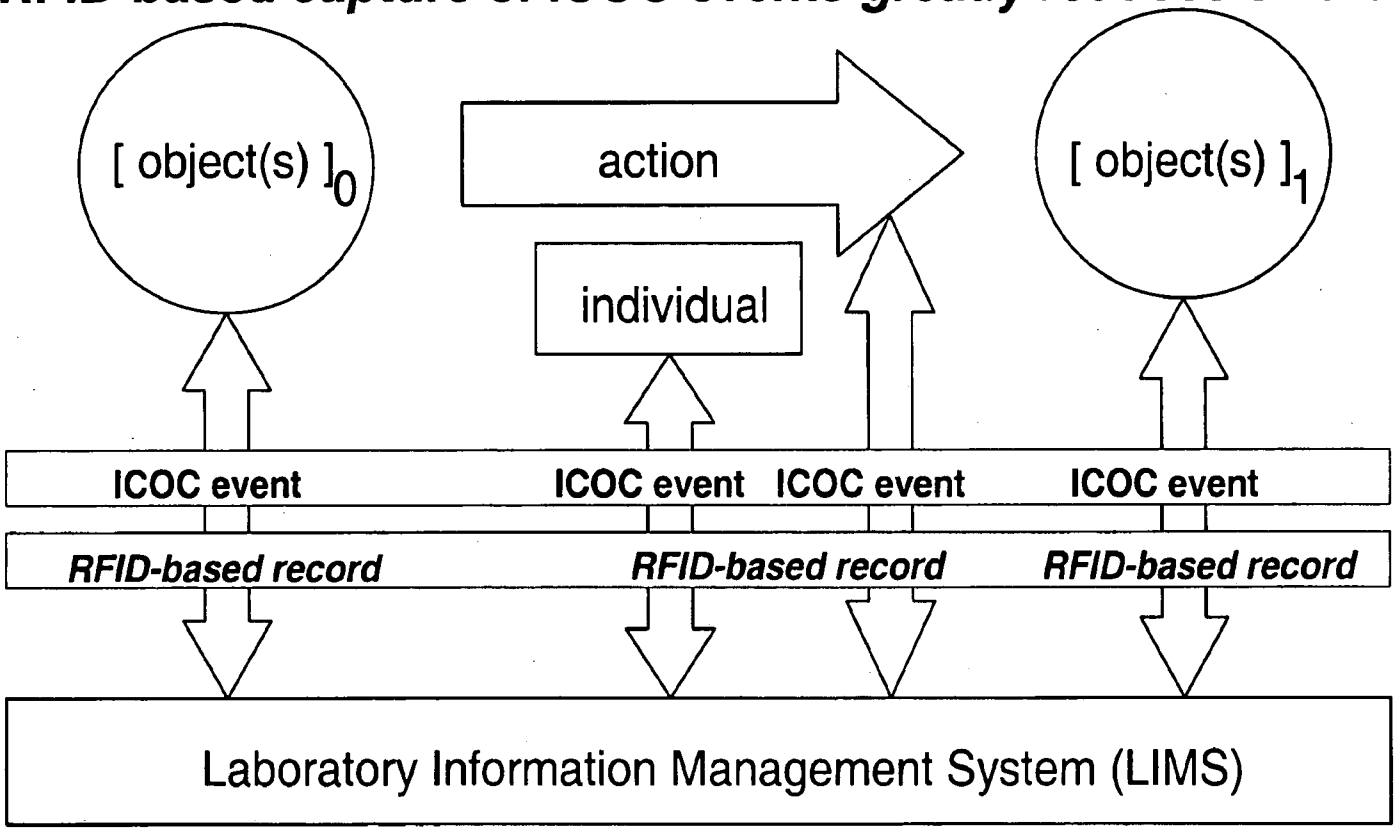
An action on an object by an individual creates an ICOC event

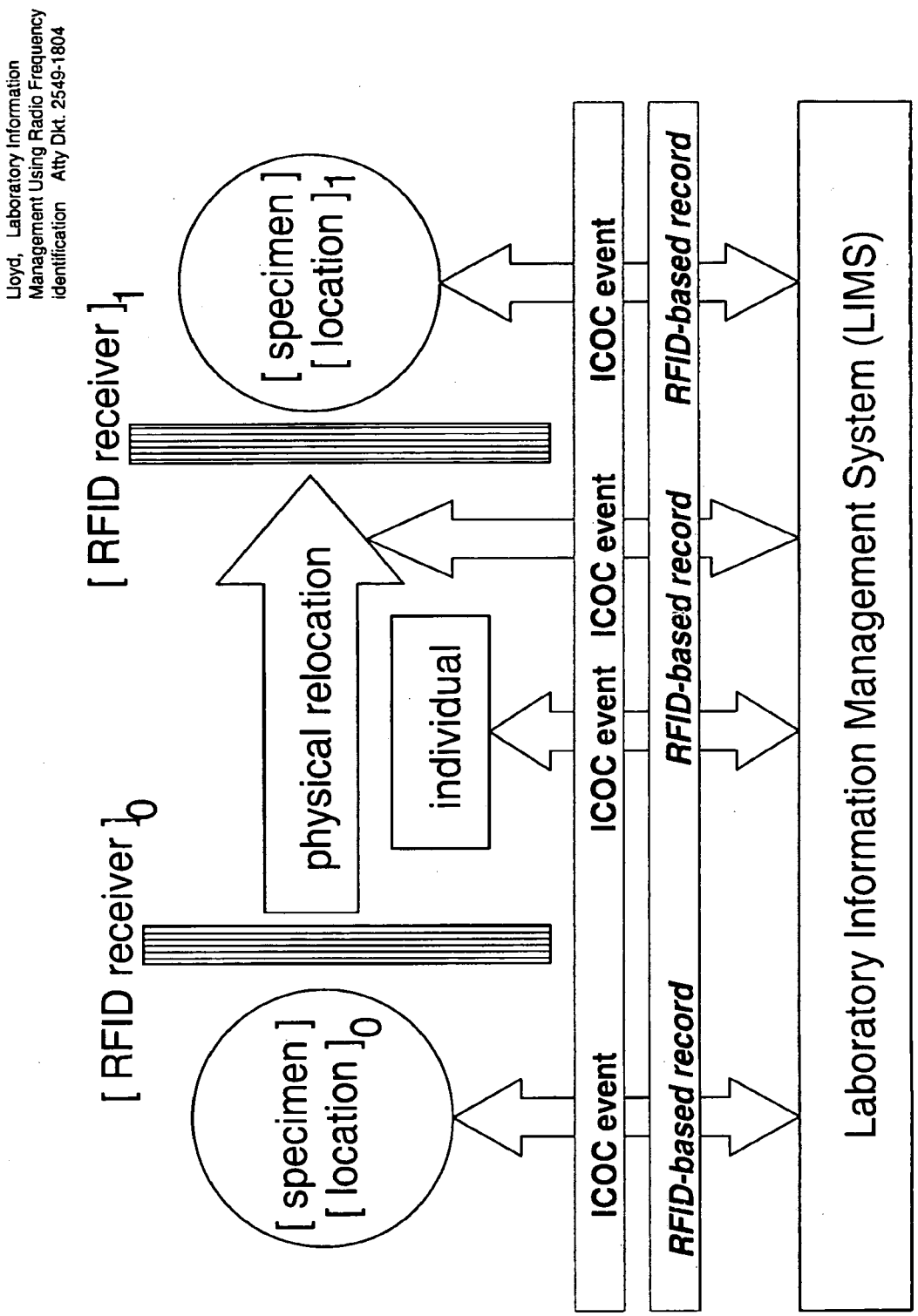


The ICOC event is captured in the LIMS by manual recording and associated data entry in the LIMS database structure



Manual data recording is error-prone
RFID-based capture of ICOC events greatly reduces errors

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physical relocation
individual
ICOC event
ICOC event
ICOC event
ICOC event
RFID-based record
RFID-based record
RFID-based record
Laboratory Information Management System (LIMS)

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