ICMP LIMS

From Grave to Grave—Electronic Chain of Custody for High-Throughput Laboratories

By Scott Strong
Bio-Informatics Manager, International Commission on Missing Persons, Sarajevo, Bosnia and Herzegovina

The use of electronic chain of custody will free technicians from paperwork and improve quality assurance by essentially eliminating human error.

INTRODUCTION

In the early 1990s, armed conflicts erupted in the former Yugoslavia, resulting in a tremendous loss of human life. By the time the conflicts ended in 1999, up to an estimated 40,000 persons were missing. The International Commission on Missing Persons (ICMP) was founded at the G-7 conference in Lyon, France, in 1996 to help resolve the fate of the missing in the former Yugoslavia. Initially, the ICMP provided financial and political assistance to organizations involved in identification and family association programs. In 1999, the ICMP began to directly build its capacity for performing on-the-ground forensic recovery and identification efforts, as well as direct involvement with family associations. By June of 2000, the ICMP began collecting blood samples from family members who were missing loved ones. In concert with this action, four DNA laboratories were constructed, each designed to address a specific DNA-testing need. The creation of a population-based DNA-led identification program was unique, and many obstacles were faced. Nonetheless, the system was established, and on November 16, 2001, the first blind DNA match was made. By the middle of 2003, 400–500 DNA reports were being generated each month. The high number of DNA reports has had a significant impact on communities within these regions, as the names, history and truth are returned to bodies in unprecedented numbers. The work continues.

INITIAL PROBLEMS

The preservation of a forensically sound chain of custody (COC) is a critical part of laboratory practice. As the ICMP continued to improve its extraction protocols, the number of profiles extracted from bone samples quickly grew. The amount of labor required to track these samples grew in parallel. A more efficient mechanism to track the COC and provide quality assurance was needed. The previous method used in ICMP's laboratories to track the COC was entirely paper-based. This required that each sample container be manually labeled in conjunction with the accompanying COC paperwork. This part of the process was negatively impacting both performance and laboratory capacity.

SOLUTION

The solution was to free technicians from filling out paperwork and labeling sample containers, while continuing to ensure that the requirements for a complete COC and quality assurance were met. Prototypes of an electronic system to fulfill these needs were developed.

CONCEPT

The ideal solution was to develop an electronic COC and quality assurance system that had the ability to view and report the progress and status for all samples at any time. To accomplish this, we designed software to electronically identify samples, technicians, workstations, equipment and chemicals used throughout the entire

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process. Data collection, monitoring adherence to protocols, quality assurance and reporting were the core values used in the development of the prototype Laboratory Information Management system. (LIMs). The following describes various aspects of the ICMP's LIM system.

LABORATORY INFORMATION MANAGEMENT SYSTEM

Security: This system requires users to log in before they can access any part of the LIMs (Figure 1). Security settings can be configured to allow or deny access to any module. This security system is also designed to prevent "brute-force" attacks on user names or passwords. The LIMs administrator can configure for each user specific times that they are allowed to log in (i.e., allow logins Monday through Friday 0800 hours until 1730 hours and exclude logins on Sunday and Saturday). If a user fails to enter the correct password on the third attempt, that account is locked out.

Database Configuration: Any sample, technician, workstation, equipment or chemical that is entered into the LIMs must first be added to the database and assigned a barcode (Figures 2 and 3). The barcode settings module establishes the range of barcodes that can be used. Any barcodes outside these ranges will be ignored by the system. The LIMs administrator has the ability to 'flag' any item in the databases as "Out of Service" (e.g., to prevent a pipette that is out of calibration from being used in any part of the LIMs, thus preserving quality assurance). The LIMs administrator also has the ability to print a complete inventory of the databases with full descriptions and barcodes.

Chain of Custody: Starting a LIMs project involves identifying three required components: sample, technician and workstation. Once the operator has scanned the barcodes and the LIMs has accepted each scan (a green

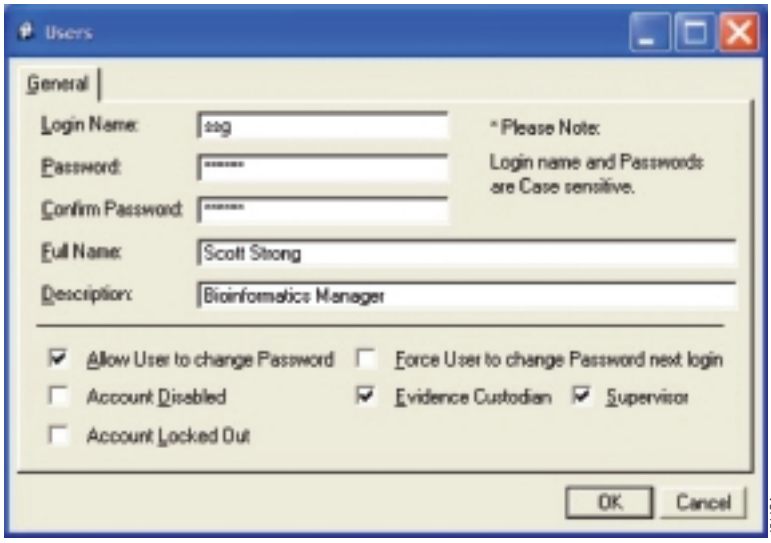

Figure 1. Users' properties window.

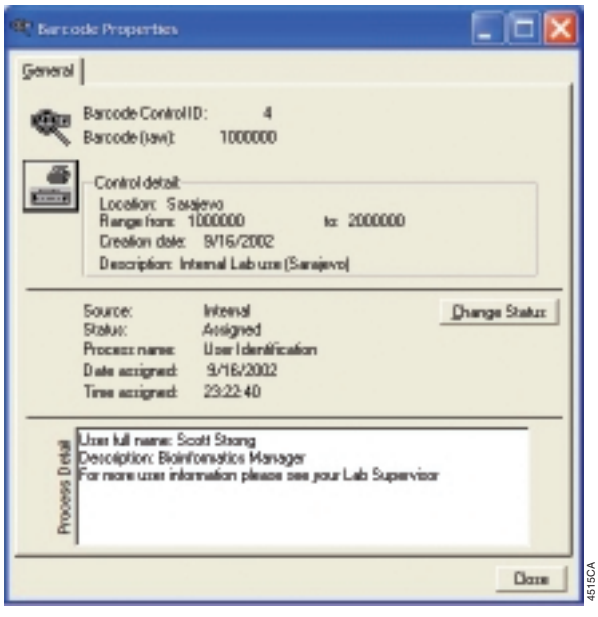

Figure 2. Barcode properties window.

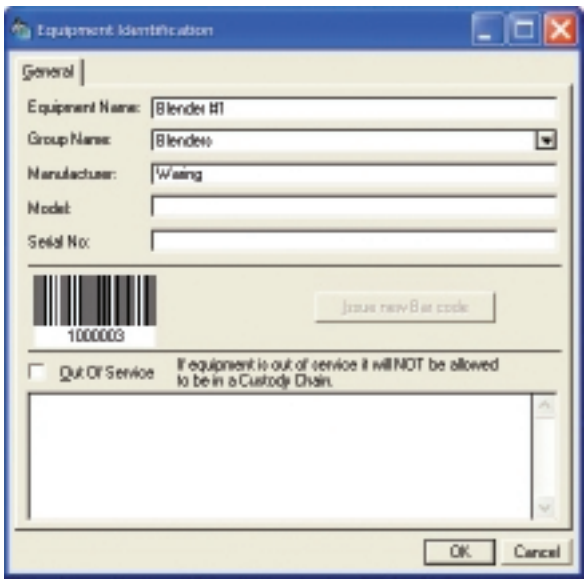

Figure 3. The equipment identification window.

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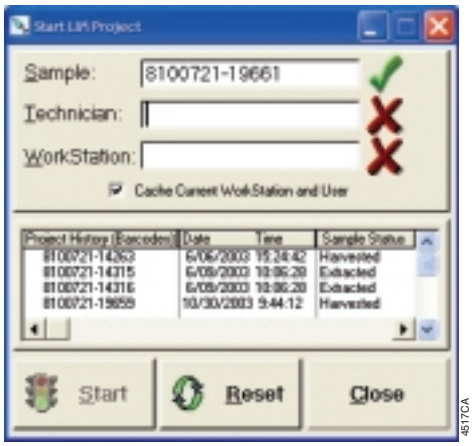

Figure 4. Start LIM Project window.

check mark will appear next to each field that has been accepted; see Figure 4), the "Start" button will become available. Clicking the "Start" button or hitting the "Enter" key will start or continue a LIMs project. If a sample is being run for the first time, the software will prompt the operator to choose a LIMs template (Figure 5). New samples do not have a project number associated with the original barcode, and when a sample is run for the first time, a new barcode is generated and printed. The new barcode includes the original sample barcode

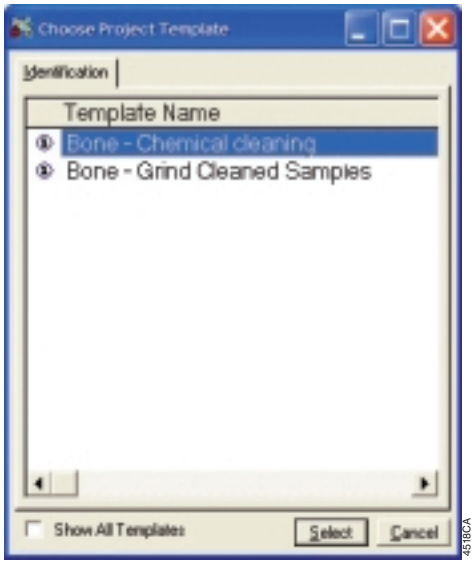

Figure 5. LIMs template selection.

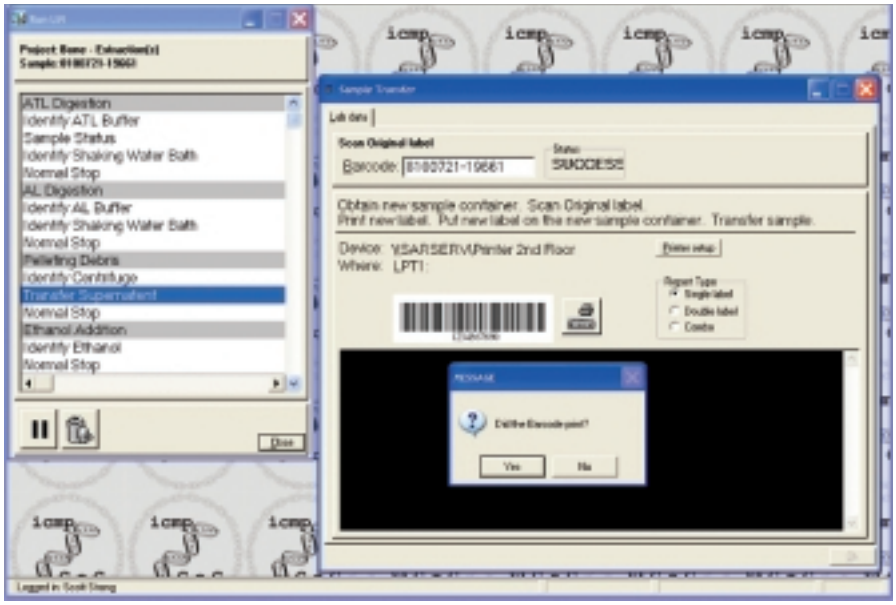

Figure 6. An example of an active LIMs project. This window is the sample transfer module.

concatenated with a unique project number. If a project (a unique LIMs run) is being run for the first time, the sample will start from the first LIMs instruction set. If a sample has started a LIMs project, it will continue from where the run was paused or where a normal stop[1] was issued. This system has several configurable modules, some of which provide instructions, data collection, sample status updates or LIMs control (see Figure 6, sample transfer module). If a technician attempts any process out of sequence, the software provides an error message informing the operator that this step is not allowed and why. The same applies if an incorrect sample, workstation, chemical, equipment or technician is "scanned." If a sample becomes tainted at any time during a run, the operator can abandon that sample. If a sample is abandoned, it cannot be used in the LIMs again. When a sample finishes a LIMs project, the sample's status is set to "complete."

LIMs Monitoring and Reporting: It is possible to view and print the status of any sample at any time. The complete chain of custody documents are available for viewing and printing from this module. This module also supports exporting COC data in either a summary or verbose format. A summary format offers the current status, while the verbose report will give you a complete COC document.

CONCLUSION

The use of electronic COC will free technicians from paperwork and allow them to concentrate on sample analysis. This type of system should also improve quality assurance by essentially eliminating human error. One benefit of the system is a reduction in the time required to process samples compared to manual COC documentation. It also provides an efficient method of tracking tens of thousands of samples and can be used to correlate problematic samples to their source.

[1]A normal stop is a LIMs module that allows an active LIMs project to pause and reset for a different sample to run.