SHIMADZU
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Technical Report

Security Measures for Protecting the Reliability of Measurement Data

1. Ensuring Reliability of Measurement Data

There are certain requirements for assuring the reliability of measurement data. One is that only eligible measurement instruments are being used, and the other is that validated measurement methods and SOPs are actually being used in measurement. Other important elements necessary for ensuring data reliability include implementation of data security measures, as well as backup and restore procedures. According to "ISO 15489-1:2001 Information and documentation -Records management - Part 1: General", it is stated that an organization should, for the necessary period of time, be able to trust the authenticity of records, create and maintain records that can be used, and protect the completeness of those records. This concept serves as a reference for implementing security measures and backup/restore procedures with respect to measurement data.

The question then becomes, "What kind of security measures and backup/restore procedures should be undertaken to ensure the reliability of measurement data?"

2. Current Situation in Analytical Laboratories

Since chromatographic instruments such as LC and GC first come to mind when considering the types of measurement data for which reliability must be ensured, there is a tendency to assume that this applies only to LC and GC. However, analytical laboratories where only LC and GC are used are relatively rare. The current situation is that a wide variety of instruments are being used in typical laboratories, including balances, total organic carbon analyzers (TOC), ultraviolet-visible spectrophotometers (UV) and Fourier Transform infrared spectrophotometers (FTIR), atomic absorption spectrophotometers (AA), and mass spectrometers (MS), etc. It is important to carefully consider the current situation of the laboratory in this manner to effectively ensure the reliability of measurement data (*see* Fig. 1). To do this, it is important to conduct a risk assessment of the impact that the measurement data generated by the various instruments can have on the substance being measured (Example: user's own products).

Fig. 1 Addressing Instruments Other Than LC and GC

3. Implementation of Data Management System

When investigating data security, and backup/restore measures, it is important to take into consideration the impact on daily operational productivity. Introduction of a system that is not suitable could lead to increased complexity of daily measurement operations, which could greatly increase the burden placed on measurement data management.

For example, if the intent is to manage multiple independent measurement instruments, this could easily become a complicated operation due to the different types of data handling that would be required for the various instruments, or cost and operation could become burdensome because of the need to separately manage the data generated by multiple instruments.

In contrast, introduction of the Shimadzu network system allows a server to collect data generated by the various types of instruments, as shown in Fig. 3, and since the measurement data is managed collectively in a secure environment, not only is the issue of security addressed, but improved productivity can also be achieved.

4. Data Falsification Risk

It is not unusual in analytical laboratories for measurement data to be collected from multiple instruments and then be combined into a single report. Spreadsheet software, such as Excel, is often used to create reports. As shown in Fig. 4, for example, only the necessary measurement values are transcribed manually to a single Excel spreadsheet from the data reports that are output from the various instruments.

The problem here is the strong possibility that errors will be made in copying the data manually. Although the probability of mistaken data input is not very high when only a few types of measurement data is being transcribed, input errors will very likely increase if more data is to be transcribed, and it will also be more difficult to catch these errors.

In this situation, even the introduction of a server to ensure measurement data security would not lower the risk associated with creating reports in this way. Thus, even if there is no intent by the author to falsify data, transcription errors can easily be mistaken for falsified data.

Fig. 2 Separate Management of Measurement Data

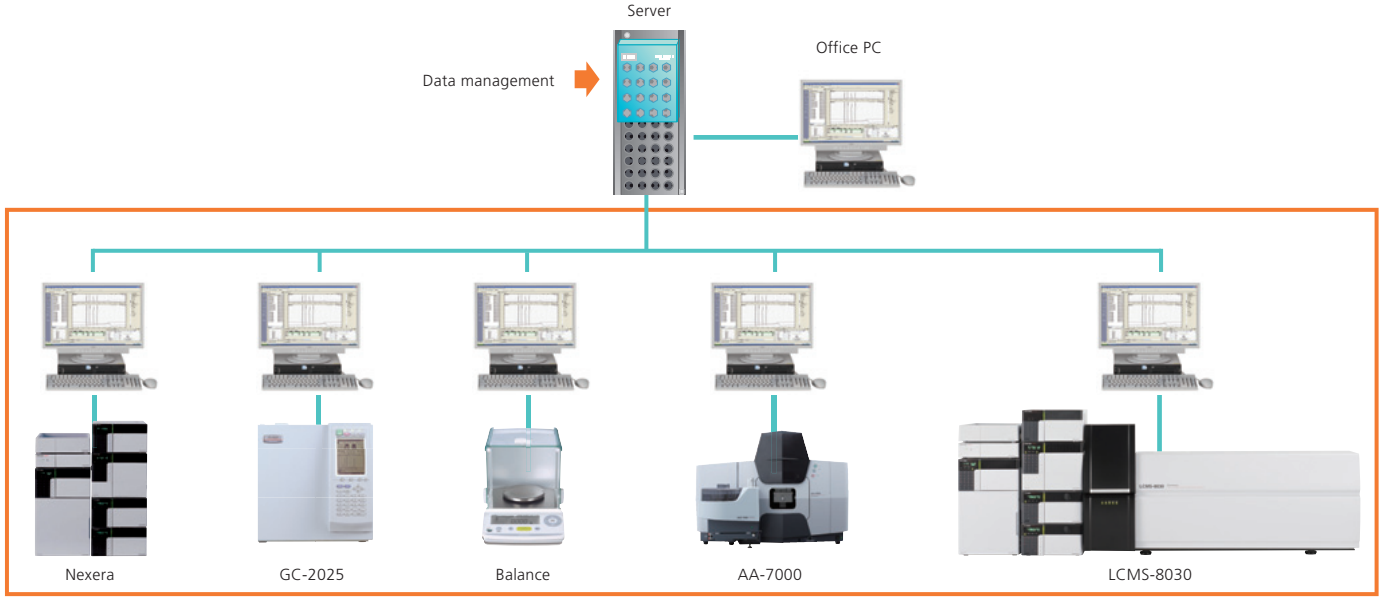

Fig. 3 Example Implementation of Shimadzu Network System

5. Reducing Risk Related to Excel Files

Since the manual input tasks shown in Fig. 4 can be automated with the Shimadzu network system, shown in Fig. 5, the risks associated with report creation can be reduced. In addition, any existing report templates (Excel files) that are being used can still be used, thereby allowing report creation to continue in a similar manner. For example, data acquired from multiple instruments can be subjected to pass/fail assessment using Excel calculation functions, and can be presented in graphical format, etc. utilizing existing templates.

The actual operation consists of storing the report template (Excel file) on the server beforehand. Then, when an analysis is completed, assuming that the measurement data and report template are specified beforehand, the specified values in the measurement data are automatically pasted into designated positions in the template (Excel file). The completed report (Excel file or PDF file format) is then automatically stored on the server.

Thus, the task of transcribing the numerical values in the measurement data to the report template (Excel file) is conducted by the server in a secure environment. Moreover, the server itself handles the management of measurement data, report templates (Excel files) and generated reports (Excel files or PDF files), thereby reducing the risk associated with creating reports using Excel.

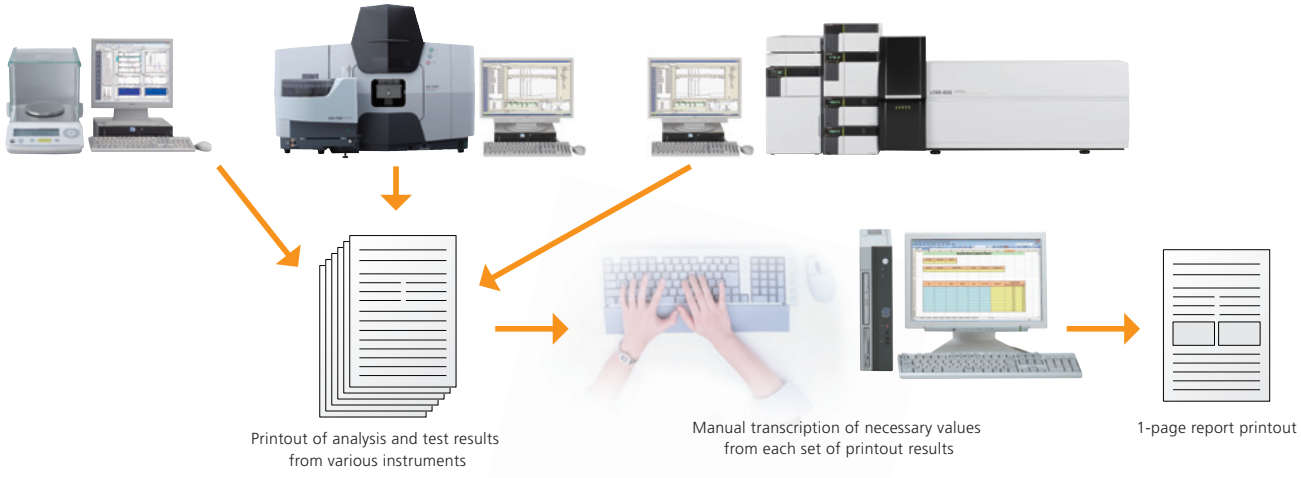

Fig. 4 Conventional Report Creation Process

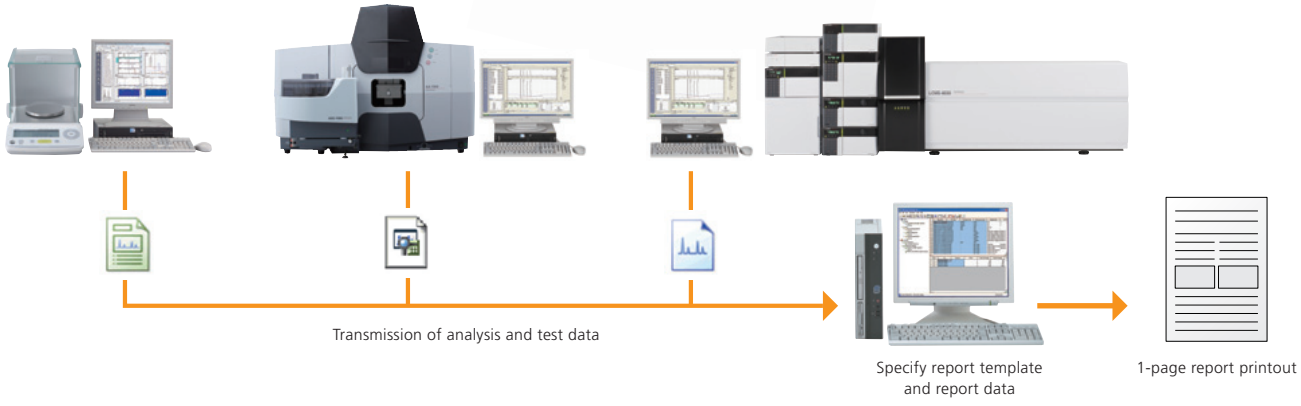

Fig. 5 Report Creation Process Using Shimadzu Network System

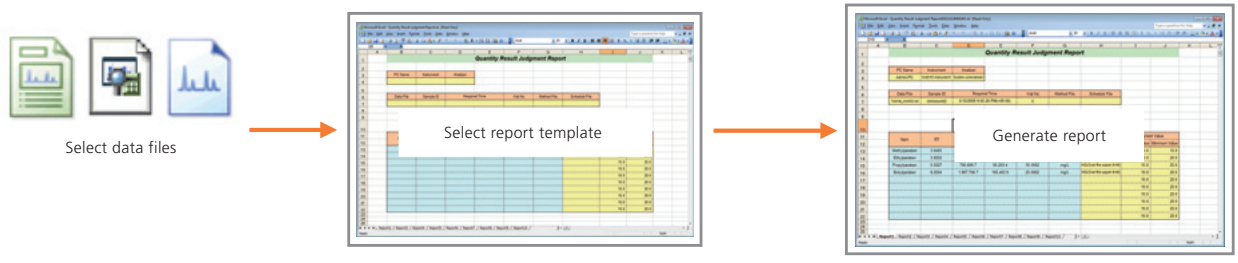

Fig. 6 Excel Report Creation Flow Using Shimadzu Network System

6. Data Search and Backup/Restore

The handling of measurement data that continuously accumulates day after day can become a brain-racking problem for the person in charge of data management. The Shimadzu network system is equipped with database functionality, so when it is necessary to retrieve measurement data that is stored on the server, the target data can be quickly located using various data sorting criteria, including conditions such as instrument name, date, etc.

On the other hand, when it comes to backing up and restoring data, the Shimadzu network system supports secure password-protected backup of data to CD and DVD. The process of restoring the backed up data is also very easy. Data that is backed up to a CD or DVD can easily be browsed by merely inserting the disk into a CD/DVD player on a PC, as long as that person also has permission to access that data.

7. Support for Data of Various Equipment Manufacturers

The Shimadzu network system not only supports measurement data management of Excel and PDF files, but also Word files, image files, etc., as shown in Fig. 8. Even data previously printed and stored as hard copies can be managed in the same way by scanning the hard copies to convert them to electronic format. This will prevent their loss due to environmental or other reasons.

In addition, the Shimadzu network system not only supports acquisition of data generated by Shimadzu instruments, but is flexible enough to support acquisition using other manufacturers' equipment as well. Because of its support for total data management in the analysis laboratory, this system contributes greatly to the reliable storage of measurement data.

8. Highly Advanced Security

The Shimadzu network system supports construction of various types of databases, including Oracle, MS SQL Server, etc. Also, in addition to user identification based on ID and password, fingerprint recognition is also supported for an even more secure environment (*see* Fig. 7).

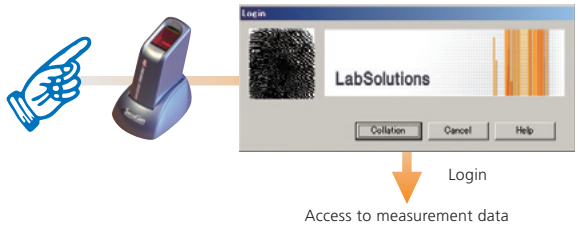

Fig. 7 Strengthened Security with Fingerprint Recognition

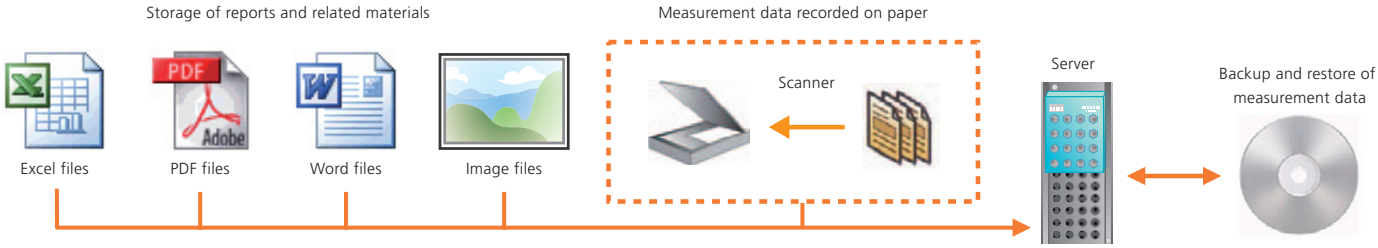

Fig. 8 Effective Searching of Measurement Data

References
JIS X 0902-1:2005 Information and Documentation – Records Management – Part 1: General
ISO 15489-1:2001 Information and documentation - Records management - Part 1: General
Shimadzu Technical Report: Agent Report: Limiting Report Creation Risks Through Automatic Integration of Various Types of Data

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