Laboratory Information Management System for Good Data and Record Management Practices

Kyungwon Suh[1]*, Kyunghun Jung[1], Tae-Hong Park[2], Jung Bo Yoo[1], and Seung Ho Kim[3]

[1]*Radioactive Waste Radiochemical Analysis Section, Korea Atomic Energy Research Institute*

[2]*Radioactive Material Chemical Analysis Section, Korea Atomic Energy Research Institute*

[3]*LIME Solution, 308, Yongsin-ro, Sangnok-gu, Ansan-Si, Gyeonggi-do*

Corresponding author: kyungwon0707@kaeri.re.kr

***Keywords:** Laboratory information management system, good data and records management practices*

1. Introduction

Nuclear Safety and Security Commission (NSSC) announced a partial revision of the regulation on the delivery of low- and intermediate-level radioactive waste with draft Administrative Notice No 2020-14, which key point of the proposed revision was introducing quality assurance obligations of waste management [1]. Afterward, it was announced that quality assurance obligations related to radioactive waste management, including characterization to be performed by generators of low- and intermediate-level radioactive waste, through a press release [2]. Therefore, the quality assurance programs for waste management were initiated by Radioactive Waste Radiochemical Analysis Section and Quality Management Division at KAERI and then launched along with being developed the quality assurance programs for waste management.

In quality assurance programs, data and records management are important for data integrity and compliance to several NSSC Notices related to waste management including Regulation on the delivery of low- and intermediate-level radioactive waste. To achieve and maintain good practices for data and records management, Laboratory Information Management System (LIMS), which is defined as computer software and hardware that can acquire, analyze, report, and manage data and information in the laboratory, was implemented and has been operating since 2021. Herein, our experience about good practice for data and records management will be introduced.

2. Status of LIMS

2.1. Definition

As mentioned above, LIMS is defined as computer software and hardware that can acquire, analyze, report, and manage data and information in the laboratory [3].

2.2. Hierarchical structure and work-flow of LIMS

The hierarchical structure and workflow of LIMS in relation to the testing work of the radioactive waste radiochemical analysis section at KAERI. Specifically, workflow of LIMS is categorized to 4 areas like Reception – Work Assignment – Results Entry – Release.

2.3 Current status of LIMS at KAERI

After development of electronic laboratory notebook and testing electronic laboratory notebook and scientific data management system during 2020, we have been operating and maintaining LIMS in accordance with Operation and Management of LIMS of Laboratory Operation Procedures at KAERI since 2021.

3. LIMS for Good Data and Records Management Practices

Good Data and Records Management Practices (GDRP) mean that the totality of organized measures that should be in place to collectively and individually ensure that data and records are secure, attributable, legible, traceable, permanent, contemporaneously recorded, original and accurate and that if not robustly implemented can impact on data reliability and completeness and undermine the robustness of decision-making based upon those data records [4]. GDRP play a significantly important role of quality assurance programs and a systematic approach should be implemented to provide a high level of assurance that all data and records are complete and reliable throughout their life cycles.

3.1. Principles for GDRP

There are some principles to achieve GDRP. First, management should establish and maintain a working environment that minimize the risk of human error during data entry.

Second, record-keeping methodologies and system should be designed in a such way that encourage compliance with the principle of data integrity. For example, restricting user access rights to system to prevent data amendments is one of methodologies and system.

Third, the system should take account of scientific and technical progress. System used to record and store data should be periodically reviewed for effectiveness and updated as necessary.

3.2. Relevance with LIMS

The first principle is maintained by reducing human errors during result entry by Scientific Data Management System (SDMS), which is computer system used to capture, centrally store, catalog, and manage data generated in a laboratory environment [3].

Record-keeping methodologies and system is guaranteed by access control which function is supported by default. This means that an only qualified person is available to enter, modify, and review data so that data and record are protected by unauthorized access.

According to the third principle, LIMS has undergone regular validation to ensure it is functioning properly and effectively. In addition to these periodical review, system validation to ensure that it meets the desired specifications and requirements is currently underway based on LIMS operation and maintenance.

4. Conclusions

Good data and records management practices are critical elements of quality assurance program for radioactive waste management. These practices are implemented and sustained through the use of LIMS, which provides support for data management, data protection, and regular validation.

REFERENCES

[1] Nuclear Safety and Security Commission, “Administrative Notice of Partially Revised Notice regarding Regulation on the delivery of low and intermediate level radioactive waste”, NSSC Notice No. 2020-14, Feb. 24, 2020.
[2] Nuclear Safety and Security Commission, “Thorough Verification and Inspection of Radioactive Wastes to Improve Safety” Press Release of NSSC, July 30, 2020.
[3] American Society for Testing and Materials, “Standard Guide for laboratory informatics”, ASTM E-1578, 2018.
[4] World Health Organization, “WHO Expert Committee on Specifications for Pharmaceutical Preparation", WHO Technical Report Series-996, 2015.

Acknowledgement

This work was supported by KAERI Institutional Program (Project No. 521320-23).