Journal of RADIATION INDUSTRY

Vol. 19, No. 3, pp. 339-345, 2025
https://doi.org/10.23042/radin.2025.19.3.339

Original article

A Study on the Quality Assurance Procedures of Radioactive Certified Reference Materials from the U.S. National Institute of Standards and Technology

Seungho Jo[1], Tae Young Kong[1,*], Changju Song[1], Jaeok Park[1], Hoyeon Lee[1], and Jiyeon Jun[1]

[1]Department of Nuclear Engineering, Chosun University, 10, Chosundae 1-gil, Dong-gu, Gwangju 61452, Republic of Korea

ABSTRACT Radioactive certified reference materials (CRMs) are crucial in various fields, such as the calibration of radiation measuring instruments, environmental radiation monitoring, and applications within the medical and nuclear industries. The discharge of contaminated water into the ocean following the Fukushima nuclear accident has raised public concern about radiation safety in Korea. As a result, the demand for radioactive CRMs in Korea is expected to continue increasing. However, the current supply system for radioactive CRMs in Korea relies solely on a single institution. This reliance raises concerns that the supply may not meet the anticipated demand in the future. Such limitations could lead to uncertainties regarding the reliability of radiation measurements at the national level and overall public safety concerning radiation. To address these challenges, the introduction of a new producer of radioactive CRMs is being proposed. Producing radioactive CRMs in Korea requires meeting specific legal and technical requirements. Among these, ISO 17034 outlines the general criteria for reference material producers, which include assessing homogeneity, monitoring stability, assigning property values, characterizing materials, determining the uncertainties of the property values, and ensuring metrological traceability of certified values. Additionally, ISO 33405 provides an approach to the requirements specified in ISO 17034. Therefore, to produce radioactive CRMs in Korea, compliance with the technical requirements set forth in ISO 17034 and ISO 33405 is essential. The National Institute of Standards and Technology (NIST) performs functions similar to those of the Korea Research Institute of Standards and Science (KRISS) and serves as a supplier of radioactive CRMs in the United States. This study examines the quality assurance procedures for radioactive CRMs developed by NIST. Their quality assurance procedures consist of 22 steps based on ISO 17034 and ISO 33405. This study analyzes these 22 steps by categorizing them into pre-production, production, and post-production phases, presenting the overall process through a schematic diagram. The findings of this study are intended to provide practical guidance for future radioactive CRM producers in Korea looking to comply with international technical standards.

Key words: Radioactive certified reference materials, Reference materials, National Institute of Standards and Technology, Quality assurance procedures

1. Introduction

The Great East Japan Earthquake in 2011 led to a nuclear fuel meltdown at the Fukushima Daiichi Nuclear Power Plant. Following the accident, the ocean discharge of radioactively contaminated treated water from the plant has been ongoing since 2023 [1-3]. As a result, the people of Korea have expressed concerns about the safety of agricultural and fishery products imported from Japan, as well as the natural radiation levels in Korea. In light of this, Korean radiation monitoring agencies are actively monitoring environmental samples, which include ocean water, soil, and imported agricultural and marine products, to ensure radiation safety [1-3]. This monitoring involves detecting radioactivity and radioactive substances. Detecting these radioactive materials in environmental samples requires high-resolution and high-efficiency radiation detectors. To maintain the accuracy and reliability of these detectors, regular calibration and verification processes are essential. Calibration and verification can be performed using certified reference materials (CRMs) [4]. A reference material (RM) is a substance

ISSN 1976-2402 **http://www.ksri.kr/**

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***Corresponding author:** Tae Young Kong
Tel: +82-62-230-7158, E-mail: tykong@chosun.ac.kr

Received 26 September 2025 **Revised** 30 September 2025 **Accepted** 30 September 2025

with well-established and homogeneous characteristics that is used for device calibration, evaluating measurement methods, or assigning property values [5]. A CRM is a type of RM that is accompanied by documentation from an authorized institution. This documentation confirms that, through valid procedures, one or more certified property values are provided along with associated uncertainties and metrological traceability [6]. Therefore, continuous environmental radiation monitoring is crucial to ensure radiation safety. At the same time, the demand for radioactive RMs and CRMs used to calibrate radiation-measuring instruments is expected to grow. However, the supply of radioactive CRMs in Korea currently depends on a single institution, the Korea Research Institute of Standards and Science (KRISS), which may not be able to meet the increasing demand.

A new producer of radioactive CRMs has been proposed to enhance the supply system for these materials in Korea. To produce radioactive CRMs, the producer must adhere to the technical requirements set by international standards. These standards include ISO 17034 (General requirements for the competence of reference material producers) and ISO 33405 (Reference materials - approaches for characterization and assessment of homogeneity and stability), which outline the necessary technical requirements and methodologies [7,8]. In the United States, the National Institute of Standards and Technology (NIST) serves as a national standards organization with functions similar to those of KRISS. The quality assurance procedures established by NIST provide a comprehensive guide for developing and producing radioactive CRMs [9]. This study analyzes the NIST quality assurance procedures and is expected to serve as a valuable reference for future radioactive CRM producers in Korea who need to meet these technical requirements.

2. Materials and Methods

In Korea, the production of radioactive CRMs is subject to specific legal and technical requirements. The primary technical standards are detailed in ISO 17034 and ISO 33405 [7, 8]. Since national standards are developed based on international standards, compliance with these national standards is effectively considered as compliance with international standards [10]. Producers intending to manufacture radioactive CRMs in Korea must analyze and adhere to the national standards that correspond to international standards, specifically KS A ISO 17034 (General requirements for the competence of reference material producers) and KS A ISO Guide 35 (Reference materials—Guidance for characterization and assessment of homogeneity and stability). KS A ISO 17034 outlines the general requirements that reference material producers must satisfy, which include stability assessments, homogeneity assessments, characterization, uncertainty assignment, and the establishment of measurement traceability [6]. Meanwhile, KS A ISO Guide 35 offers guidance on the methodologies related to the requirements specified in KS A ISO 17034 [11].

The NIST, which operates similarly to the KRISS in the U.S., has published procedures for producing radioactive CRMs. These procedures outline how to meet the requirements of ISO 17034 and ISO 33405. They are organized into 22 steps, covering the pre-production, production, and post-production phases of radioactive CRMs [9]. This study analyzed the NIST quality assurance procedures to understand how they incorporate the requirements of ISO 17034 and ISO 33405 and to provide an overall analysis of the process. In Korea, these materials are referred to as radioactive CRMs, while in the NIST documentation, they are called radioactive standard reference materials (SRMs). For consistency, this study will refer to them as radioactive CRMs throughout.

3. Results and Discussion

ISO 33405 provides a comprehensive overview of the stages involved in the production and maintenance of RMs [8]. This overview includes several key phases: defining the RMs, acquiring materials, processing, packaging, assessing homogeneity, evaluating stability, preparing certificates, and monitoring stability. It also addresses commutability assessment and characterization, both of which are essential for certifying RMs. The RM's definition phase specifies the RM's matrix, the properties to be characterized, the required levels, the intended use of the material, and the uncertainty of the CRMs. For the characterization, as well as the homogeneity and stability assessments, it is crucial to select appropriate measurement procedures. Particularly for CRMs, the measurement results for each property value must be traceable to both international and national standards. Figure 1 illustrates this overview [8]. Additionally, the NIST quality assurance procedure for producing radioactive CRMs is structured in accordance with the RM production overview presented in ISO 33405.

3.1. Pre-production procedures for radioactive CRMs

The NIST quality assurance procedures outline the pre-pro-

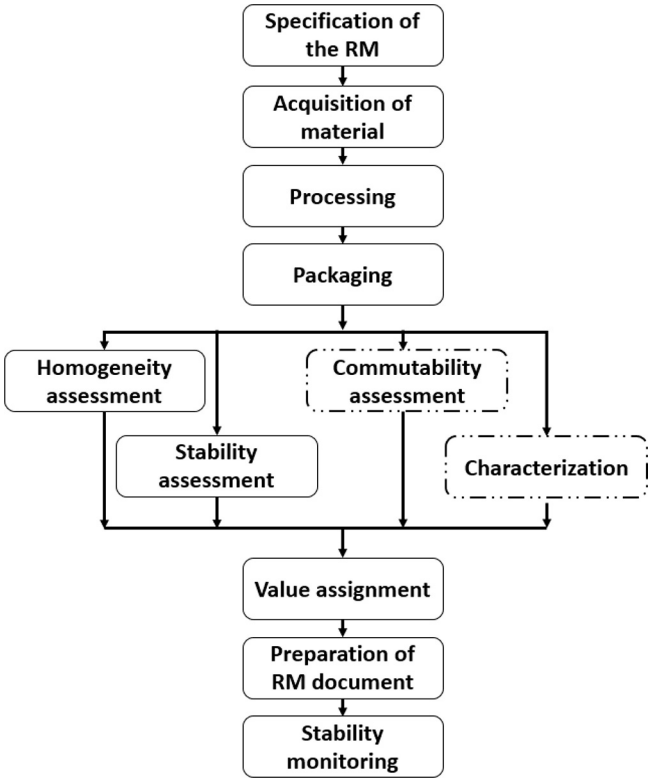

Fig. 1. Outline of a Reference Material Project: A Schematic Overview

duction phase of radioactive CRM production, divided into a total of eight steps [9]. The first step involves clearly defining the purpose and intended use of the radioactive CRM. This establishes the criteria for the entire production process and includes setting quality goals and acceptable uncertainty limits. Uncertainty is a key factor that affects the reliability, certification, and utilization of a radioactive RM. In the second step, physical and chemical properties of the radioactive CRM must be selected. Characteristics like the radionuclide's half-life, the type of radiation emitted, activity, and the sample form are crucial as they influence the final application of the CRM. This step ensures homogeneity assessment, stability assessment, and characterization of the material. The third step requires the producer to select suitable containers and packaging materials for the CRM. Materials such as borosilicate glass or Teflon ensure chemical stability, while packaging materials are classified into Type A, B, and C grades according to IAEA-SSR-6 (Regulations for the Safe Transport of Radioactive Material) [12]. These containers and packaging not only provide storage stability for the radioactive CRM but also prevent leakage during transport. In the fourth step, the producer finalizes the measurement model, sampling, and measurement methods. This step involves using high-precision equipment like high-purity germanium (HPGe) detectors and liquid scintillation counters (LSC). A well-designed measurement method is essential for securing measurement traceability for the radioactive CRMs. The fifth step requires a comprehensive review and approval of the radioactive CRM production process. This review assesses whether the production plan and experimental design meet regulatory requirements and user needs, with particular attention to procedures for handling radioactive materials and the safety management system. The sixth step involves a thorough review and approval of safety measures for the entire radioactive CRM process. The producer must implement radiation shielding facilities, laboratory environmental monitoring devices, and safety interlock systems to minimize worker exposure and prevent environmental contamination. These safety measures must be managed continuously through regular inspections and updates. In the seventh step, the producer must secure funding and obtain budget approval for the development and production of the radioactive CRM. The allocated funds are used for facility construction, equipment calibration, material procurement, labor costs, and quality control activities. Documentation of fund usage ensures transparency and serves as a reference for future projects. The final step, the eighth, involves preparing facilities, equipment, and personnel for the production of the radioactive CRM. The producer must calibrate and install key equipment such as HPGe detectors, microbalances, and ventilation systems. All personnel must complete radiation safety training. Afterward, a pre-operational run verifies that the facilities and personnel are functioning normally, and any issues must be addressed immediately. This step is crucial as it serves as the final verification before entering the main production phase.

The NIST quality assurance procedures outline the pre-production process for radioactive CRMs through eight key steps. This phase primarily involves defining the CRM's main use and purpose, securing necessary materials, and reviewing both the production process and safety measures. A summary of these pre-production procedures for radioactive CRMs is provided in Table 1 [9].

3.2. Procedures during production of radioactive CRMs

The in-production phase for radioactive CRMs is divided into nine steps, Steps 9-17, which encompass the actual manufacturing and characterization processes [9]. In Step 9, the producer acquires the appropriate materials for producing the radioactive CRM. The radionuclides used must be of high purity and

Table 1. Pre-production processes and necessary facilities outlined in the NIST quality assurance procedures for radioactive CRMs

Steps	Description	Required Facilities & Equipment
1. Determine use, requirements, and demand	Define development objectives and intended use, such as calibration, environmental monitoring, medical and industrial applications, and establish the range of uncertainties	-
2. Select chemical and physical properties	Select physical and chemical properties (radionuclides, half-life, activity concentration, sample form)	Stability testing equipment, chemical analysis instruments
3. Select a suitable container and packaging	Select containers and packaging materials (use borosilicate glass and Teflon containers for safe storage; apply IAEA Type A, B, C packaging regulations)	Mechanical strength tester, radiation shielding tester
4. Select a measurement model, a suitable sampling and measurement method	Select measurement model and methods (HPGe detectors, LSC, sampling methods)	HPGe detector, LSC, data analysis software
5. Proposed production process reviewed and approved	Review and approve the production process and experimental design for compliance with regulatory and safety requirements	Document review system, quality management tools
6. Proposed safety measures reviewed and approved	Review and approve safety measures (radiation shielding, environmental monitoring, safety interlock system)	Radiation monitors, environmental monitoring systems
7. Obtain the necessary funding	Secure funding and approve budget for facilities, calibration, materials, labor costs, and quality management activities	-
8. Arrange for the use of the necessary facilities, equipment, and personnel	Prepare facilities, equipment, and personnel (installation and calibration of instruments, safety training, pilot operation)	HPGe detector, ventilation system, microbalance

undergo quality inspections during procurement to prevent the introduction of impurities. Additionally, solvents and non-radioactive carriers must be of at least analytical grade and include traceable component analysis data. These materials ensure the reliability of the subsequent production process. In Step 10, the producer mixes the radionuclides and solvents to prepare the radioactive CRM solution or solid sample and performs characterization. The mixing process is designed to ensure that all sample units maintain uniform concentration, utilizing high-precision weighing equipment like microbalances. After mixing, the materials are inspected to confirm their physical homogeneity and chemical stability. In Step 11, validation of the preparation methods takes place. The radioactive CRM producer creates pilot samples to evaluate the accuracy and reliability of the mixing and weighing procedures, identifying potential errors in advance. The results of this validation are documented and stored as quality assurance data. In Step 12, the producer uniformly dispenses the prepared radioactive CRM solution into containers. This process employs precision liquid dispensers to ensure that each container receives the same volume and concentration. After dispensing, random samples are extracted and inspected to confirm they meet the specified criteria. In Step 13, the homogeneity of the radioactive CRM is assessed. The producer randomly selects several produced units and measures property values, such as radioactivity concentration, using statistical analysis to confirm that deviations between units fall within acceptable ranges. If homogeneity is not achieved, the production process is re-examined, and corrective measures are implemented. In Step 14, the producer measures the property values of the radioactive CRM. Key values such as radioactivity concentration, gamma-ray energy, and half-life are measured using high-precision equipment like HPGe detectors. The measurement results are processed according to international standards, calculating the mean, standard deviation, and uncertainty using statistical methods. In Step 15, a stability assessment of the radioactive CRM is performed. This assessment verifies whether the CRM can remain stable without physical or chemical changes over the long term by storing and analyzing samples under conditions that are similar to, or more severe than, the actual use environment. In Step 16, the producer assigns the final property values and uncertainties to the radioactive CRM. These values are calculated from the collected data to determine the mean and confidence intervals. Uncertainty reflects all potential variables, including equipment errors, environmental factors, and analytical procedures. The finalized property values and uncertainties are then recorded on the certificate and

Table 2. Production procedures and necessary facilities outlined in the NIST quality protocols for radioactive CRMs

Steps	Description	Required Facilities & Equipment
1. Acquire suitable materials	Secure high-purity radionuclides and at least analytical-grade reagents	Spectrum analyzer, quality inspection equipment
2. Prepare and characterize the materials	Ensure mixing homogeneity, confirm physical and chemical stability	Microbalance, mixing device, HPGe detector, and other high-resolution equipment
3. Validate preparation methods (pilot tests, method validation)	Create pilot samples, validate mixing and weighing procedures	Homogeneity test equipment, high-precision detector
4. Dispense the CRM solution (or mixture) into the CRM containers	Ensure uniform concentration and volume using a precision liquid dispenser	Precision liquid dispenser, Teflon, and glass containers
5. Measure the homogeneity among (and possibly within) CRM units	Compare units using random sampling and statistical analysis	High-resolution equipment such as HPGe detectors, statistical analysis software
6. Measure the value of each selected property as obtained directly or indirectly	Calculate property values such as radioactivity concentration, radiation energy, and half-life	High-resolution equipment such as HPGe detectors, radiation measurement devices
7. Stability assessment (short-term, long-term)	Verify the stability of physical and chemical properties under short- and long-term conditions	Environmental control devices (temperature and humidity regulators)
8. Characterization and assignment of the uncertainties of the property values	Calculate confidence intervals and uncertainty through statistical analysis	Statistical analysis software, calibrated standard materials
9. Metrological traceability of certified values	Ensure traceability (connection) to the international system of units using certified reference materials	Calibration equipment, standard materials traceable to international standards

provided to the user. Securing measurement traceability of the radioactive CRM is the final step (Step 17). This ensures that the measured values can be linked to the international system of units through internationally recognized calibration procedures and RMs. The radioactive CRM certificate must specify the equipment, calibration method, and RM information used to secure traceability. The reliability and international usability of a radioactive CRM are validated through its certificate.

The NIST quality assurance procedures detail the production phase of radioactive CRMs through Steps 9 to 17. Key aspects of this phase include assessing homogeneity, measuring property values, evaluating stability, characterizing samples, and ensuring traceability. Table 2 summarizes these procedures [9].

3.3. Post-production procedures for radioactive CRMs

The post-production phase for radioactive CRMs, which encompasses Steps 18 to 22, involves distribution, management, and process improvement based on user feedback [9]. In Step 18, the producer safely packages the dispensed radioactive CRMs. These materials are first sealed in ampoules or Teflon containers and then double-protected with packaging designed to provide both radiation shielding and shock absorption. The primary goal of this step is to prevent radioactive leakage during transport and storage while ensuring the stability of the samples against environmental changes. After packaging, the seals are re-checked for leaks, and any defective samples must be promptly discarded or reprocessed. In Step 19, the producer documents the entire radioactive CRM production process. This includes recording all pertinent details, such as radionuclide selection, mixing methods, property value measurements, and traceability procedures in a standardized format. This data and documentation are stored in a central management system for future verification and audits, ensuring transparency and reproducibility. This thorough documentation serves as a reliable basis for quality management that regulatory bodies can trust. In Step 20, the producer prepares and distributes the official CRM certificate. This certificate includes the CRM's property values, uncertainty, traceability information, and supplementary details like usage instructions, storage conditions, and safety precautions. Issued in both physical and digital formats, this certificate demonstrates that the CRM complies with international standards, allowing users and regulatory bodies to access

Table 3. Post-production procedures and necessary facilities for the NIST quality control measures related to radioactive CRMs

Steps	Description	Required Facilities & Equipment
1. Label, package, and store the CRM containers	Sealing the CRM and packaging it for radiation shielding and shock absorption	Sealing equipment, radiation-shielding packaging materials
2. Document the production process	Recording and preserving the procedures for radionuclide mixing, measurement, and securing traceability	Data management system
3. Prepare the CRM certificate	Issuing a certificate that includes property values, uncertainty, measurement traceability, and usage instructions	Document creation software, electronic certification system
4. Collect and store the production records	Systematically storing measured values, uncertainty, and calibration records	Cloud storage and backup servers
5. User feedback and improvement	Obtaining and reflecting user feedback on the CRM, and improving the production process, including packaging, certificates, and procedures	User survey system, survey data analysis tools

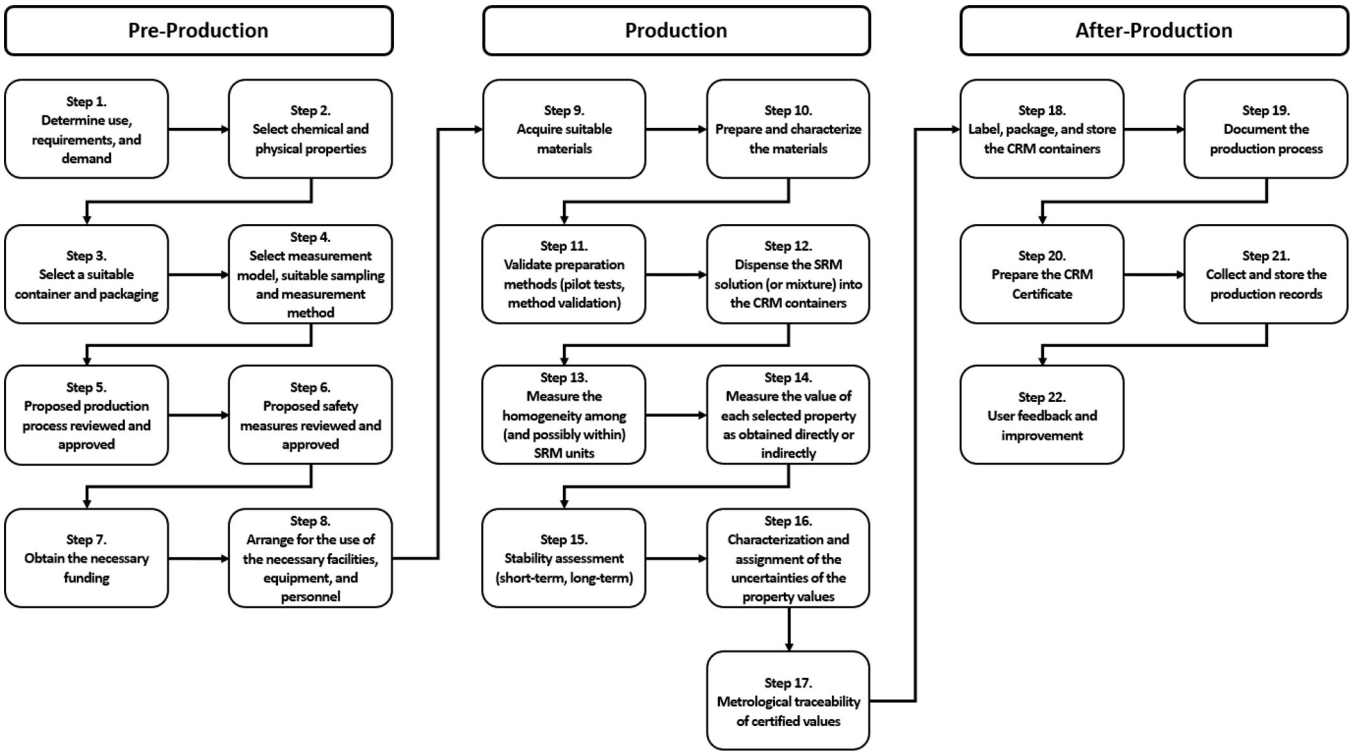

Fig. 2. An Overview of the 22 Steps in the NIST Quality Assurance Procedures for Producing Radioactive CRMs

and rely on it equally. Step 21 involves storing the radioactive CRM data, which includes measured values, uncertainty calculations, calibration records, and sampling and analysis logs. To ensure data integrity and security, this information is stored redundantly in a cloud repository and on backup servers, with regular backups and encryption in place. This systematic data management allows for a quick response to requests from regulatory agencies or user inquiries. In the final step (Step 22), the producer collects user feedback and utilizes it to improve the radioactive CRM production process. Feedback is gathered through various methods, including surveys, performance evaluations, and reviews of the certificate's clarity. This feedback is analyzed by the quality management system. Common issues or requests for improvement are integrated into the production process, leading to specific actions such as changing packaging materials, enhancing certificate formatting, and optimizing procedures. This feedback loop improves the quality and usability of the CRMs, thereby strengthening the producer's international credibility.

The NIST quality assurance procedures detail the post-pro-

duction steps (18-22), which include essential elements such as packaging for distribution, certification, and the integration of user feedback. Table 3 provides a summary of the post-production procedures and the necessary facilities involved [9]. Additionally, this study presents an overview of the procedures for pre-production, production, and post-production of radioactive CRMs in Fig. 2 [9].

4. Conclusion

Radioactive CRMs are crucial in several fields, such as the calibration of radiation measuring instruments, environmental radiation monitoring, medical diagnostics, and industrial applications. Following the Fukushima nuclear accident, the release of contaminated water into the ocean has heightened public concern about radiation safety in Korea. As a result, there is a growing need for high accuracy and reliability in radiation safety practices, particularly in environmental radiation monitoring and radiation measurement. Consequently, the demand for radioactive CRMs in Korea is expected to continue increasing. Currently, the supply system for radioactive CRMs in Korea is dependent on a single institution, which is anticipated to be insufficient to meet the rising demand. This limitation may create uncertainties in ensuring the reliability of national radiation measurements and in safeguarding public safety. To address this issue, the introduction of new radioactive CRM producers has been consistently proposed. Any producers wishing to manufacture radioactive CRMs must comply with both legal and technical requirements. Among these, the technical requirements must align with international standards such as ISO 17034 and ISO 33405. ISO 17034 outlines the general requirements for the competence of reference material producers. Its key elements include assessing homogeneity, stability, characterization, assignment of property values, evaluation of uncertainties, and establishing metrological traceability. ISO 33405 provides additional standards that outline how to meet the major requirements specified in ISO 17034, detailing methods and practices to ensure compliance. Therefore, new radioactive CRM producers must adhere to the specifications laid out in ISO 17034 and ISO 33405.

This study examined the quality assurance procedures for radioactive CRMs developed by the NIST in the United States. The procedures are organized into 22 steps, aligned with the requirements of ISO 17034 and the RM production framework outlined in ISO 33405. These steps are categorized into three phases: pre-production, production, and post-production. The study provides a detailed analysis of each phase and summarizes the findings in a schematic diagram. The results of this study are anticipated to serve as a valuable reference for new radioactive CRM producers in Korea as they strive to meet the technical requirements of both international and national standards.

Acknowledgments

This work was supported by the Korea Institute of Energy Technology Evaluation and Planning (KETEP) and the Ministry of Trade, Industry, and Energy (MOTIE) of the Republic of Korea (No. RS-2024-00349003).

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