Journal of RADIATION INDUSTRY

Vol. 19, No. 2, pp. 193-199, 2025
https://doi.org/10.23042/radin.2025.19.2.193

Original article

Legal and Technical Requirements for Radioactive Certified Reference Materials in Korea

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ABSTRACT Following the recent discharge of treated radioactive water from the Fukushima Daiichi nuclear power plants into the ocean, public interest in radiation safety has significantly increased in Korea. As a result, ensuring the accuracy and reliability of radiation measurements for imported seafood and goods distributed in Korea has become a key societal concern. Accurate and traceable measurements of radioactivity require the calibration of instruments using certified reference materials (CRMs). Consequently, there is a growing demand for radioactive CRMs across various sectors in Korea, including environmental monitoring, nuclear power, and medical applications. However, the Korea Research Institute of Standards and Science (KRISS) is currently the sole institution responsible for developing and producing radioactive CRMs in the country. This study aims to identify and analyze the legal and technical requirements that institutions must fulfill to be recognized as producers of radioactive CRMs. The legal framework includes the Framework Act on National Standards, the Conformity Assessment Management Act, and the Korea Laboratory Accreditation Scheme (KOLAS) accreditation operational guidelines. On the technical side, the study examines the essential implementation of 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), which provide internationally accepted guidelines for CRM production. Additionally, quality system documentation from the National Institute of Standards and Technology (NIST) in the United States is reviewed to offer comparative insights. The findings of this study aim to support the development of a nationally coordinated CRM production system that meets both Korea's needs and international standards.

Key words: Reference materials, Certified reference materials, Requirements, Korea Laboratory Accreditation Scheme, Korean Standards

1. Introduction

In 2023, the release of treated radioactive water from the Fukushima Daiichi nuclear power plants in Japan into the ocean raised public concerns about radiation safety in Korea. Specifically, there has been growing anxiety regarding the radiation safety of agricultural and aquatic products produced in areas near the Fukushima facility. To address these concerns, it is essential to have highly accurate and reliable radiation measurements [1]. This requires radiation measurement instruments to be properly calibrated using radioactive certified reference materials (CRMs). Consequently, the demand for radioactive CRMs for calibrating radiation measurement devices is expected to increase, driven by the need for precise and trustworthy radiation measurements.

In nuclear power plants, whole-body counters (WBCs) are used to assess internal exposure to radioactive nuclides ingested by workers, which are calibrated with gamma-emitting mixed-nuclide standards [2]. Ensuring radiation safety for residents near nuclear facilities necessitates periodic radiation analysis of radioactive discharges into the environment. High-purity germanium (HPGe) detectors are commonly used for this pur-

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

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Received 13 June 2025 **Revised** 17 June 2025 **Accepted** 17 June 2025

pose and require continuous calibration with radioactive CRMs [3]. Additionally, the decommissioning of nuclear power plants involves the use of various radiation and radioactivity measurement devices for the classification, treatment, and disposal of radioactive waste, thereby further increasing the demand for calibration-grade radioactive CRMs.

Currently, the Korea Research Institute of Standards and Science (KRISS) is the only institution in Korea responsible for the development and distribution of radioactive CRMs [4]. In the future, the demand for radioactive CRMs in various industries in Korea is expected to grow, and there is a possibility that domestic supply through KRISS alone may not be sufficient. Therefore, this study investigates and presents the legal and technical requirements for establishing domestic institutions to produce radioactive certification standard materials, aiming to enhance the supply of radioactive CRMs.

2. Materials and Methods

A reference material (RM) is a substance with sufficiently homogeneous properties and well-established property values, used for calibrating measurement devices and validating analytical methods [5]. A radioactive CRM is a type of reference material that comes with a certificate issued by a competent authority, detailing specific property values along with their associated uncertainties and traceability to validated procedures [6]. These materials are crucial for instrument calibration, method validation, and quality control in various fields that involve radioactivity measurements.

This study systematically analyzed the legal and technical framework for producing radioactive CRMs in Korea. Three main legal requirements were reviewed: the Framework Act on National Standards, the Conformity Assessment Management Act, and the operational guidelines of the Korea Laboratory Accreditation Scheme (KOLAS) [5,7,8]. First, the Framework Act on National Standards was evaluated to understand the qualifications and duties required for institutions intending to become radioactive CRM producers in Korea. These producers must obtain accreditation for the production of radioactive CRMs through KOLAS, adhering to national standards and procedures necessary for official certification [9]. The study also reviewed the Conformity Assessment Management Act and its enforcement regulations to confirm the requirements and procedures for obtaining national accreditation. Additionally, the KOLAS accreditation operational guidelines were examined to explore the application process for accreditation and the technical requirements necessary for radioactive CRM producers.

This study examined the national standards 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) [6,10,11]. KS A ISO 17034 outlines the general requirements for the competence of CRM producers, focusing on aspects such as quality management systems, human resources, equipment, quality documentation, uncertainty evaluation, traceability, and record management. On the other hand, KS A ISO Guide 35 provides detailed procedures for the characterization of reference materials, as well as the assessment of their homogeneity and stability. It includes statistical methodologies that are essential for the certification of CRMs. These standards encompass key elements, including experimental design, sampling plans, method validation, statistical data analysis, and uncertainty estimation. Together, they provide a comprehensive framework to ensure the reliability and traceability of CRMs.

3. Results and Discussion

3.1. Legal requirements for radioactive CRM producers in Korea

Technical capabilities alone are insufficient for the development and distribution of radioactive CRMs in Korea; legal requirements must also be met. This study examines the legal requirements for radioactive CRM producers by reviewing the Framework Act on National Standards, the Conformity Assessment Management Act, and the KOLAS accreditation operational guidelines. The Framework Act on National Standards establishes the overall national standardization system. It provides a structural framework for both the private sector and the government to participate in the development and utilization of national standards. This act lays the groundwork for standard materials to function not just as samples, but as essential components that support national measurement reliability [5]. Article 4 of the Act, which outlines the Responsibilities and Duties of the State, stipulates that universities, research institutes, businesses, and public institutions must proactively engage in the development of national standards and strive to ensure that the results can be utilized effectively [5]. Additionally, Article 15, concerning the Certification and Diffusion of Reference Materials, mandates that the government actively promote the

certification and distribution of standard materials necessary for precise measurement, property evaluation, and instrument calibration [5]. As a result, the development and production of radioactive CRMs are not limited to specific institutions but are accessible to various organizations that meet the necessary requirements.

The Act on the Management of Conformity Assessment outlines the procedures and necessary documentation for institutions seeking recognition as accredited producers of standard materials. This law enables conformity assessment agencies to evaluate and accredit various institutions, including calibration laboratories, testing facilities, and certification agencies, in line with international standards [7]. The primary purpose of this legislation is to enhance the standard certification system in Korea, aligning it with global practices. According to Article 7 (Establishment of Accrediting Agency) of the Act and Article 4 (Establishment of Accreditation Agency) of its Implementing Decree, the Minister of Industry, Trade, and Energy is responsible for establishing the KOLAS under the National Institute of Standards and Science [7]. KOLAS is tasked with evaluating and accrediting conformity assessment agencies. Institutions looking to produce RMs must obtain recognition for RM production through conformity assessment conducted by KOLAS. This process demonstrates their capability to provide reliable testing, inspection, and calibration results. Specifically, institutions aiming to produce radioactive CRMs must adhere to the accreditation procedures established by KOLAS. Additionally, relevant laws and regulations outline the necessary documents for applying for accreditation, which include details on human resources, equipment inventory, quality management manuals, and materials verifying technical capabilities.

The identification of specific procedures and requirements for radioactive CRM producers to be recognized as conformity assessment agencies was carried out by reviewing the KOLAS accreditation operational guidelines [8]. These guidelines outline the procedures for recognizing applications. To obtain recognition, an institution must first submit an application, which is followed by several steps: a document review, an on-site inspection, and a technical review. During the document review, the submitted materials are evaluated to determine if they meet the required criteria. The on-site inspection involves a visit to the applicant's facility to verify the adequacy of human resources, equipment, and quality systems. The technical review assesses whether the measurement and analysis capabilities of the institution are effective and comply with international standards [8]. The accreditation application process is summarized in Fig. 1. Additionally, the operational guidelines specify the required composition of technical personnel that RM producers must maintain. For instance, the quality manager and technical manager must have relevant education and practical experience specific to their roles. At the same time, staff members must demonstrate competencies in experimental performance, uncertainty estimation, and certificate issuance. These human resource requirements are essential for ensuring the reliability and reproducibility of RMs and CRMs, rather than simply being administrative requirements. Particularly, the KOLAS accreditation operational guidelines emphasize that the evaluation focuses on whether the quality system maintained by RM producers complies with the requirements of KS A ISO 17034 and KS A ISO Guide 35 [6,8,10]. These evaluation criteria are core technical requirements that ensure the quality and reliability of radioactive CRMs. Table 1 summarizes the recognition and evaluation criteria for accredited standard material production institutions as outlined in the KOLAS accreditation operational guidelines [8]. Compliance with legal requirements directly correlates with fulfilling these technical requirements.

The KOLAS accreditation operational guidelines state that evaluations are conducted to determine whether the quality systems maintained by producers align with the requirements of international standards ISO 17034 (General requirements for the competence of reference material producers) and ISO Guide 35 (Reference materials – Guidance for characterization and assessment of homogeneity and stability). In Korea, Korean Standards (KS) are established by adopting the International Organization for Standardization (ISO) standards, and compliance with KS is regarded as equivalent to compliance with ISO [12]. Consequently, producers of radioactive CRMs must undergo an accreditation evaluation based on KS A ISO 17034 and KS A ISO Guide 35 to ensure their technical systems align with ISO requirements. To produce radioactive CRMs in Korea, producers must meet three legal requirements: secure institutional legitimacy through the Framework Act on National Standards, obtain legal status as accredited RM producers through the Conformity Assessment Management Act, and undergo an evaluation of their technical capabilities and compliance with quality system standards as outlined in the KOLAS accreditation operational guidelines. By fulfilling these requirements, producers of radioactive CRMs can create materials that are recognized both in Korea and internationally.

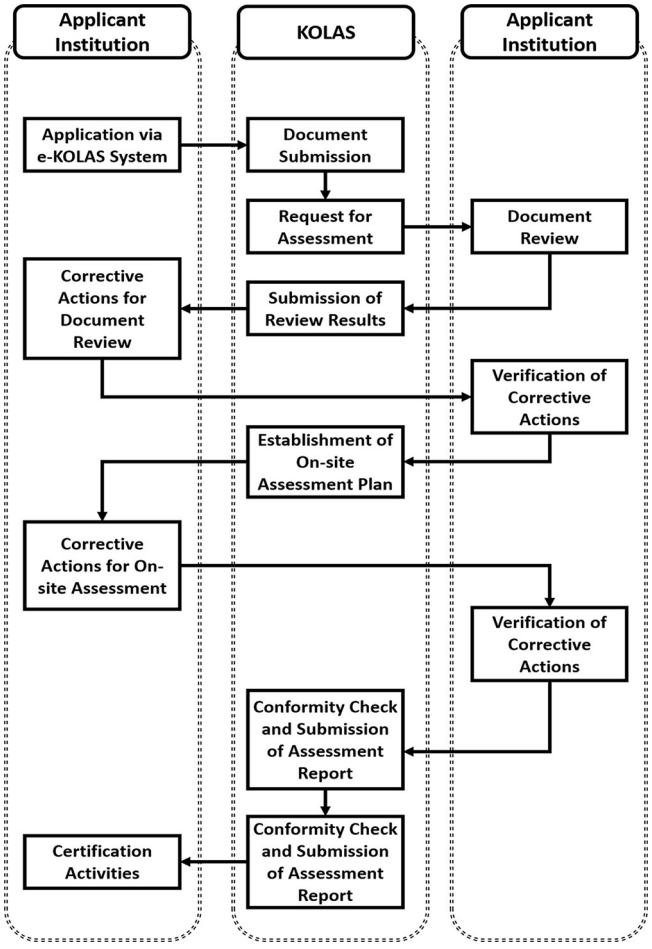

Fig. 1. Accreditation process for radioactive CRM producers in accordance with the KOLAS accreditation operational guidelines.

3.2. Technical Requirements for Radioactive CRM Producers in Korea

Producers of radioactive CRMs must not only have the appropriate production facilities and measurement technologies but also adhere to internationally recognized technical standards. The KOLAS outlines general requirements based on ISO standards and KS standards for accrediting CRM producers. This evaluation assesses the competence of reference material producers in accordance with these standards. This study focuses on the essential technical requirements that radioactive CRM producers in Korea must meet, particularly 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). Additionally, quality system documentation from the National Institute of Standards and Technology (NIST) in the United States was reviewed to benchmark international technical practices.

Since KS standards are based on ISO standards, compliance with KS is considered equivalent to compliance with ISO [12]. KS A ISO 17034 outlines comprehensive requirements for producers of RMs and CRMs. This includes aspects such as organizational structure, responsibilities and authorities, quality policies, document management systems, and technical requirements like human resource management, environmental conditions of production facilities, and the calibration and maintenance of measurement equipment. Additionally, the standard details critical processes necessary for evaluating the technical competency of CRM producers. These processes include material characterization, homogeneity assessment, stability evaluation, assignment of certified values, uncertainty estimation, and the establishment of traceability. It is important to note that the specific technical requirements vary depending on whether the material is classified as an RM or a CRM, with these differences summarized in Table 2 [10]. For producers preparing for accreditation, the KS A ISO 17034 commentary published by

Table 1. Criteria for accreditation and evaluation of standard material production institutions based on KOLAS operational guidelines

Accredited institution	Criteria for accreditation and evaluation
Accredited CRM producer	KS A ISO 17034 [General requirements for the competence of reference material producers (ISO 17034)]
	KS A ISO Guide 35 [Reference materials - guidance for characterization and assessment of homogeneity and stability (ISO Guide 35)]
	KS A ISO Guide 31 [Reference materials - contents of certificates, labels and accompanying documentation (ISO Guide 31)]
	KOLAS operational guidelines for the use of the accreditation mark and claims of accreditation status
	Guidelines for estimation and expression of measurement uncertainty
	Basic guidelines for the management of technical records of accredited institutions
	Guidelines for maintaining the traceability of measurement results
	Commentary on KS A ISO 17034

Table 2. Production requirements for RMs and CRMs

General requirements	RMs	CRMs
Production planning	Required	Required
Production control	Required	Required
Material handling and storage	Required	Required
Material processing	Required	Required
Measurement procedures	Required	Required
Measuring equipment	Required	Required
Data integrity and evaluation	Required	Required
Metrological traceability of certified values	Not required	Required
Assessment of homogeneity	Required	Required
Assessment and monitoring of stability	Required	Required
Characterization	Required, where values are to be assigned	Required
Assignment of property values	Required, where values are to be assigned	Required
Assignment of the uncertainties of the property values	Not required	Required for certified values
RM documents and labels	Required	Required
Distribution service	Required	Required
Control of quality and technical records	Required	Required
Management of non-conforming work	Required	Required

KOLAS provides further explanations and is a vital resource [11].

KS A ISO Guide 35 complements KS A ISO 17034 by providing detailed scientific and statistical methodologies for characterization processes. It covers experimental design, analytical methods, and statistical procedures essential for validating the reliability of certified values [6]. The guide includes assessments of homogeneity to ensure uniform properties across all CRM units, as well as stability assessments that evaluate changes in property values over time. Additionally, it addresses property value assignment, uncertainty assignment, and metrological traceability, which are core elements mandated by KS A ISO Guide 35. These elements are crucial technical requirements for CRM producers, ensuring the international recognition and reliability of their RMs and CRMs.

For comparative analysis, this study reviewed the quality system documentation published by the NIST, which is responsible for supplying radioactive Standard Reference Materials (SRMs) in the United States [13]. In this context, the term SRM is equivalent to CRM. The NIST quality manual outlines the entire process for developing SRMs, which is divided into 22 steps that include planning, material acquisition, experimental design, characterization, certificate issuance, and record management [13]. Notably, steps 19 to 22 align directly with the core elements of KS A ISO 17034 and KS A ISO Guide 35, covering aspects such as uncertainty assignment, metrological traceability, and management of production records. The process is summarized in Fig. 2 [13]. Since the NIST procedures are based on ISO standards, they are expected to serve as valuable references for producers of radioactive CRMs in Korea as they prepare for accreditation.

In summary, producers of radioactive CRMs must adhere to the technical requirements outlined in KS A ISO 17034 and KS A ISO Guide 35 for KOLAS accreditation. They need to demonstrate proficiency in human resource management, resource operations, testing technologies, and statistical analysis. By referring to the NIST quality system documentation, producers in Korea can align their systems with international standards. Compliance with these technical requirements is essential not just for formal recognition but also for ensuring the scientific reliability, accuracy, and legal validity of radioactive CRMs. Strengthening these capabilities is expected to enhance the stability of the supply of radioactive CRMs and improve international credibility, ultimately contributing to the reliability and accuracy of radiation measurements in Korea.

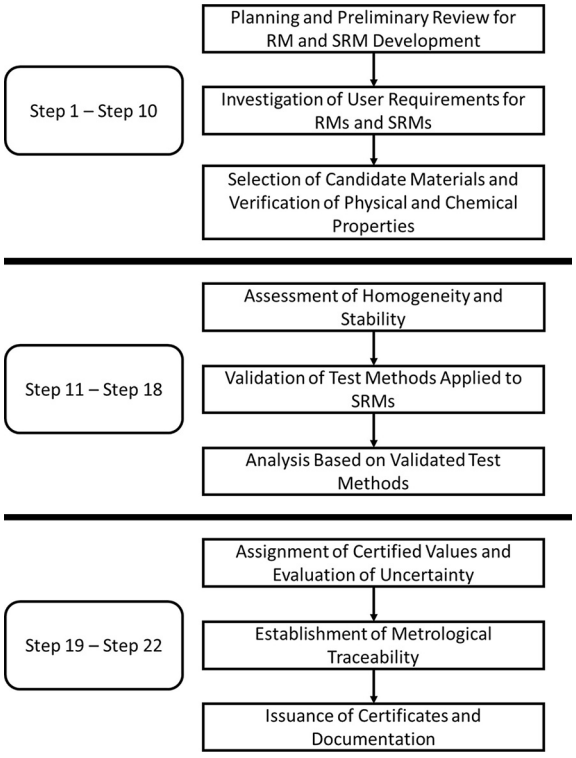

Fig. 2. Step-by-step development process of radioactive SRMs at NIST.

4. Conclusion

This study systematically analyzed the legal and technical requirements for producers of radioactive CRMs in Korea to ensure a stable production and supply of these materials. On the legal side, the Framework Act on National Standards provides the institutional foundation for the government to promote the development and production of RMs and CRMs, encouraging participation from both the public and private sectors. Additionally, the Conformity Assessment Management Act and its associated regulations outline the procedures and requirements for accreditation by KOLAS. This includes document reviews, on-site inspections, and technical evaluations that assess quality management systems, technical capabilities, and human resource expertise. On the technical side, KS A ISO 17034 and KS A ISO Guide 35 are essential standards for ensuring the quality and reliability of CRMs. KS A ISO 17034 details comprehensive requirements, such as organizational structure, human resource management, equipment management, production processes, and quality documentation. Meanwhile, KS A ISO Guide 35 provides specific technical standards, including experimental design, statistical analysis, uncertainty assignment, and metrological traceability for assessing characterized values.

The quality system documentation of NIST in the United States was reviewed to provide a reference for aligning Korea's practices with ISO standards. Notably, the latter steps of NIST's 22-step development process are directly aligned with KS A ISO 17034 and KS A ISO Guide 35, which offer practical guidelines for record management, certificate issuance, and quality reviews.

The demand for radioactive CRMs in Korea is expected to grow in sectors such as nuclear power, environmental radiation monitoring, and the medical and pharmaceutical industries. To meet this increasing demand, it is essential for producers of radioactive CRMs to establish infrastructure that complies with both legal and technical requirements while operating under an accredited certification system. The legal and technical framework proposed in this study can serve as a valuable reference for producers looking to develop their radioactive CRM production infrastructure and prepare for KOLAS accreditation. Furthermore, these efforts are expected to enhance the international competitiveness of Korea’s radioactive CRMs and ensure the scientific reliability, accuracy, and legal validity required in the global market.

Acknowledgments

This work was supported by the National Research Foundation of Korea (NRF) grant funded by the Korean government (MSIT) (RS-2023-00261937).

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