

Comparative Analysis of IAEA Safety Standards and Domestic Regulations in International Trade of Consumer Products containing NORM

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1. Introduction

International trade of commodities containing radioactive materials takes various forms, and regulatory agencies in each country are monitoring imports and exports of these to ensure radiological safety [1]. Disputes may arise if the radiological safety standards and confirmation system are significantly different between the exporting and importing countries in the trade. In particular, with regard to international trade of commodities containing naturally occurring radioactive materials (NORM) such as raw materials (Ex. Zircon dioxide, Monizite, Potassium compounds, Heavy mineral sand), NORM residues (Ex. Phosphogypsum, Red mud), consumer products (consumer products manufactured by processing or using raw materials or NORM residues), which are justified and have a relatively low risk, it is recommended that safety standards and confirmation system are consistently applied to the importing and exporting countries in order to unnecessarily hinder the trade. In Korea, regulations on consumer products containing NORM have been strengthened due to the Monazite-added radon-emitting mattress incident in 2018. Therefore, at this point of time, it is necessary to review the domestic regulations and criteria on international trade of consumer products containing NORM in comparison to the relevant international safety standards. In this study, the differences are identified by comparative analysis of IAEA safety standards and domestic regulations on international trade of consumer products containing NORM. Based on these, the referential implications for improving domestic regulation have been derived from the perspective of international harmony.

2. International Safety Standards

IAEA safety standards mainly related to the radiological safety in international trade of consumer products containing NORM are the GSR Part 3 requirements (2014) [2] and the RS-G-1.7 guides (Application of the Concepts of Exclusion, Exemption and Clearance, 2004).

2.1 IAEA GSR Part 3 Requirements [2]

According to the paragraph 3.4 of GSR Part 3 requirements, in case of exposure from NORM exceeding the activity concentration standards (K-40

10Bq/g, 1Bq/g for U and Th series), the requirements for the planned exposure situation are applied. Otherwise, the requirements for the existing exposure situation are applied. A situation of exposure due to radionuclides of natural origin in food, feed, drinking water, agricultural fertilizer and soil amendments, construction materials and residual radioactive material in the environment is treated as an existing exposure situation regardless of the activity concentrations of the radionuclides concerned.

The major planned exposure situation requirements applied to consumer products containing NORM are Requirement 7 (Notification and authorization), 8 (Exemption and clearance), Requirement 10 (Justification of practices), Requirement 12 (Dose limits) and Requirement 33 (Consumer products). Justification criteria are presented that exemptions and approvals should be ensured only for justified practices. Unjustified practices include practices that result in an increase in activity, by the deliberate addition of radioactive substances or by activation, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person. And practices involving the frivolous use of radiation or radioactive substances in commodities or in consumer products such as toys and personal jewelry or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation are also deemed to be not justified. Dose limits criteria are presented that an annual effective dose limit for the public shall be established and complied at 1mSv. Criteria for the consumer products are presented that consumer products that may cause exposure shall not be provided to the public except those that have been exempted or approved for public use. Regulatory review procedure for approval of application and supplier's compliance is also presented.

The GSR Part 3 requirements for consumer products containing NORM to which existing exposure situation applies are the establishment of strategic goals and appropriate reference levels for the management of existing exposure in accordance with paragraph 5.4. In addition, according to Requirement 48, it is presented that protection measures for the public shall be justified and optimized. According to Requirement 51, it is presented to establish an annual effective dose of about 1mSv as a reference level for the management of exposure to radionuclides in commodities.

2.2 IAEA RS-G-1.7 Guides (2004) and Revision Status

The RS-G-1.7 (2004) guides are being revised in accordance with the revision of the requirements [2] to maintain hierarchical consistency. Currently, 12th out of 14th revision steps are in progress. The review by the relevant IAEA safety standards committee has been completed, hence details will be confirmed soon without major changes.

Paragraphs 7.6 to 7.14 of the 11th revision step version of the guides (DS499) [3], which are currently available online, contain information on radiological safety management in international trade of commodities containing radioactive materials. Paragraphs 7.6 through 7.11 can be summarized as the procedure diagram in Figure 1, and the summary of the additional guidance presented in paragraphs 7.12 and 7.13 is as follows.

(7.12) Confirmation that a non-food commodity meets the screening values should be obtained at the first point of entry into trade.

(7.13) Arrangements should be made to determine the actual activity concentration levels in commodities either by obtaining the information from the supplier or by monitoring organized by the regulatory body or relevant authority.

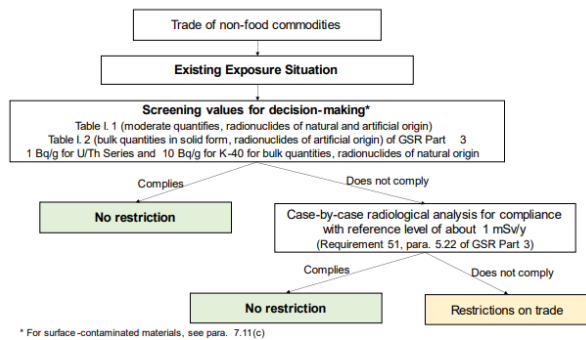


Fig. 1. Flowchart illustrating the use of screening values for decision-making in trade of non-food commodities [3].

2.3 Summary of IAEA Safety Standards

A summary of the regulatory decision steps and related safety standards for international trade of consumer products containing NORM recommended by IAEA safety standards is as follows.

[STEP 1] Determination whether to apply to existing exposure situations (necessities, less than the activity concentration standard), planned exposure situations (other than daily necessities, higher than the activity concentration standard).

[STEP 2-1] When applying the existing exposure situation, regulatory decisions whether to restrict trade are made at the time of customs clearance through an

annual effective dose reference level of about 1mSv established to optimize radiation protection. The detailed process is recommended as shown in Fig. 1.

[STEP 2-2] When applying planned exposure situation, regulatory decisions whether to restrict trade are made at the time of customs clearance by verifying the compliance with requirements of notification, approval, exemption, clearance, dose limit (1 mSv/y), justification of practices, consumer products and so on.

3. Domestic Regulatory Status

Domestic regulatory requirements for international trade of NORM-containing consumer products are based on the ‘Act on Protective Action Guidelines against Radiation in the Natural Environment’, and its supplementary guidelines are safety guidelines [4] based on Article 8 of the Act.

The main requirements are the definition of NORM-containing consumer products and quantitative standards for these (Article 2), standards for registering the product manufacturers (Article 9), reporting obligations of registered manufacturers when importing and exporting products (Article 11), obligations and standards on the record, storage and reporting of distribution of products by registered manufacturers (Article 12), safety standards for the products (Article 15), and radiation monitoring standards for the products imported through airport or port to confirm and control whether this substance is suspicious one (Article 19).

In the safety guidelines [4], the safety confirmation procedure for domestic import of consumer products containing NORM is presented as shown in Figure 2. Radiation safety standards for import control are the same as these for control of domestic distribution. In the case of commodities containing NORM, such as crop fertilizers except for consumer products, they are passed unless the surface dose rate exceeds 10 μ Sv/h. However, when a cargo loaded with consumer products passes through a radiation portal monitor, an alarm above the detection level sounds, it is subject to isolation and reporting to regulator.

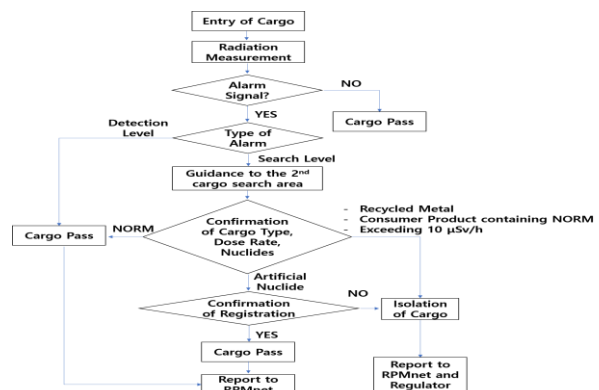


Fig. 2. Domestic airport and port radiation monitoring system safety management procedures [4]

4. Comparative Analysis and Implication

The analysis results of differences between domestic regulations and IAEA safety standards (*Step 1, 2-1, 2-2*) presented in Section 2.3 and implications derived are summarized in Table I.

5. Conclusions

In this study, a comparative analysis was performed between the IAEA safety standards and domestic regulatory standards in relation to the confirmation of radiation safety in international trade of NORM-containing consumer products. As a result of the analysis, several differences were found and their implications were derived. Based on the results of this study, it is necessary to further analyze the specific regulatory decision cases of domestic and foreign trade in the future to derive specific regulatory improvement items if necessary. These researches are expected to contribute to the continuous improvement of domestic regulations on radiations in living areas in harmony with international safety standards while considering domestic characteristics such as public acceptance.

REFERENCES

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Table I: Comparison results and derived implications

	Regulatory Decision Step 1	Regulatory Decision Step 2-1	Regulatory Decision Step 2-2
IAEA safety standards	Determination whether to apply to existing exposure situations (necessities, less than the activity concentration standard), planned exposure situations (other than daily necessities, higher than the concentration standard)	When applying the existing exposure situation, regulatory decisions whether to restrict trade are made at customs clearance through an effective dose reference level of about 1mSv/y. Detailed process is recommended in Fig. 1.	When applying planned exposure situation, regulatory decisions whether to restrict trade are made at customs clearance by verifying compliance with requirements of dose limits, justification, consumer products, and so on
Domestic Regulations compared to IAEA safety standards	In case of consumer products containing NORM, there is a product manufacturer registration system to determine whether to apply the existing or planned exposure situation. However, unlike the IAEA standards, there is no system that regards consumer products among daily necessities as an existing exposure situation regardless of the activity concentration	If activity concentration of the NORM-containing consumer product is lower than the registration standard, it is treated as an existing exposure situation and managed by applying a reference level in IAEA standards. However, in Korea, the dose limit for the general public applied for planned exposure situation is applied	The domestic requirement corresponding to the 'justification of practices' requirement in IAEA standards is Article 15 ② of the Act; (1) products with raw materials added to produce radiation effects, (2) body-adhesive products prohibited. However, it is difficult to regard (1) as a criterion for determining whether the product is justified for general use
Derived Implication	It is necessary to review whether there are domestic products that need to be managed in the existing exposure situation regardless of the activity concentration	It is necessary to review to apply 1mSv/y standard as a reference level rather than the dose limit for consumer products under the existing exposure situation	It is necessary to review the need for more comprehensive justification requirements and procedures for radioactivity in consumer products