

Comparative Study to Establish a Feasible Regulatory Framework for a Radiation Processing Plant in Kenya

Zephania Mege Odhiambo^a, Byeong-Soo Kim^b

^a*Department of Nuclear and Quantum Engineering KAIST 291 Daehak-ro, Yuseong, Daejeon 305-701, Korea*

^b*Korea Institute of Nuclear Safety, 62 Gwahak-ro, Yuseong, Daejeon 34142, Korea*

^a*zephmege@kaist.ac.kr*

1. Introduction

Radiation processing, one of the applications of advanced radiation science technology is widely accepted in many areas of the global economy with the potential to improve the quality of lives [1]. It is recognized as an energy efficient technology that has contributed to advancements such as polymerization, polymer crosslinking and gemstone colorization; as well as, the sterilization of pharmaceutical and healthcare products in addition to the irradiation of food and agricultural products. Many manufactured products critical to protecting, promoting and enhancing life including medical products and devices are irradiated to guarantee their safe utilization [2].

The International Irradiation Association (IIA) estimates that irradiation is used to sterilize about 45% of all single-use medical devices globally [3] with about 55 countries currently approving the utilization of irradiation dominantly in North America followed by Europe, Asia and the rest of the world [4].

In regulating ionizing radiation, regulators combine the tools and strategies of a regulatory framework with social values and goals to ensure the mandate of provision of safety and protection to the public and the environment is met. The enabling factors for a regulatory framework are the presence of a national policy and strategy for safety and a supportive national legal environment encouraging compliance by the industry players. To ensure effective safety and security the regulatory framework must be strong to guarantee safety as irradiators utilize high spectrum doses. It is also essential for the different regulatory bodies in that country to cooperate and collaborate with each other effectively to ensure no gaps or overlap exist in their regulatory oversight duties.

This comparative study was developed in response to the interest by Kenya, a country of about 44 million people, to add radiation processing to address the problems of industry, job creation, food security and sterilization of pharmaceutical and medical products. The study describes the concept of regulatory style and its contribution to the regulatory framework of a country. Based on these characteristics the paper will classify Kenya's regulatory style to ascertain the current status of the Kenyan regulatory framework thus understand its effectiveness and if it meets international and peer requirements for regulation of advanced radiation technology.

This paper was developed based on the analysis of the existing regulatory framework of Kenya in comparison to the well-established regulatory frameworks of relevant country regulators. These countries were selected to represent the diverse regulatory styles of radiation processing regulation in Europe, Asia and the US.

2. Methodology

The study involved a review of regulatory frameworks of case study countries utilizing radiation processing, including regulatory legislation, codes of conduct, and standard operating procedures (SOPs) focusing on the regulatory framework style. This information was then compared with the Kenyan style and offered suggestions on areas of improvement so as to make the legislation more effective. Further reference was made to the recommendations of the international regulatory oversight organizations.

The well-established frameworks of the US NRC, Korea's NSSC, Britain's ONR and Germany's BFS (Bundesamt für Strahlenschutz) were selected for study and clustered based on their application of the technology and their regulatory framework strength and style. These parameters provide a unique insight into the regulation style and its effectiveness. These countries also represent the diverse regulatory styles of radiation processing regulation in Europe, Asia and America.

3. Results and Discussion

3.1. Global Status of Irradiation Industry

Geographically, the global irradiation market is dominated by North America, followed by Europe, Asia, and the Rest of the World [5]. The IIA estimates that the use of electron beam and gamma irradiators account for about 45% of all single-use medical devices. Figure 1 below shows this distribution. Based on this significance of irradiation currently accounting for almost half of the world sterilization market coupled with increasing interest by developing countries like Kenya to incorporate irradiators, the need and importance to consider safety as these irradiators utilize very high spectrum ionizing radiation in the order of 30 kGy and up to 250 kGy in case of polymer crosslinking is high.

About 500,000 metric tons of food products are commercially irradiated per year. This is realised by about 55 countries who have approved the utilization of irradiation.

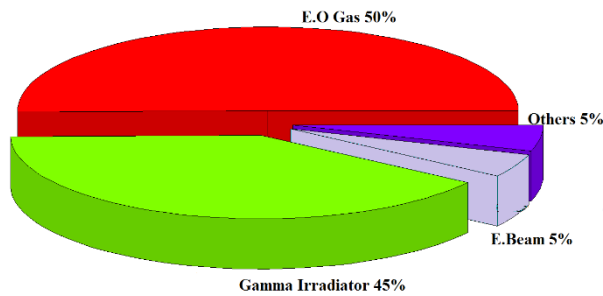


Figure 1: Breakdown of Global Sterilization Market

3.2 The concept of regulatory style

The central role of any government is to protect its citizens by regulating the relationship between public and private sector through tools, strategies and goals in a framework. Regulatory style thus is the design of a framework based on the political and administrative while concentrating on the specific policy types meant to motivate behavioral change. Thus, frameworks can be differentiated in design seen on evaluation of its peers. The research thus considered this difference in the regulatory framework informed by the political system, design of the regulatory law and the environment of regulation. This classification system shows the effectiveness of a regulatory framework in comparison to other styles.

Politics both current and past influence the direction of a country's regulation. A country's law is greatly influenced by its colonizers and its history that's why socialist nations have conspicuously punitive, strict and somewhat dictatorial laws whereas capitalist/democratic systems are considered more tolerable. The current political administration in power also influences and affects the regulatory framework through tools bestowed upon it. A classic example is the decision by Germany despite their well-established regulatory regime of BSF with a history of safety in regulation of advanced radiation science opted to shut down its nuclear sector in favor of renewables as was the desire of the ruling administration. Thus, the intertwined nature of the regulation and politics

The design of the legislation is also a factor to consider in the style. The existence of legislation, its rigor, and how well thought out enough it is to addresses all the possible foreseeable eventualities especially in radiation processing. The legal and regulatory authorities instituted and the level of correctness in the regulatory requirements are factors that influence the monitoring systems put in place to detect and identify noncompliance and the necessary actions

The implementation of the law plays a huge role in determining the categorization of the regulatory style. The thoroughness in the implementation, the environment under which its implemented plays a factor. If both the environment and legislation are in sync then

safety is enhanced. The regulator easily detects cases of noncompliance and applies necessary enforcement tools does to address it. The monitoring and enforcement regime should be commensurate to each other especially in radiation process that can utilize up to 250 kGy. Based on the factors above the paper classified frameworks into three.

3.2.1 The Old Commonwealth Style

The study recognized this as a style of regulatory approach since it influenced the framework of former colonies of the British Empire especially Kenya whose framework is under study. Since the radiation protection laws were first passed when it was still British colony and the laws amended in 1982 to improve it but still borrowed heavily from the British version. This is because of the Political connection to Britain by virtue of being their colonizer, and the framework having only provisions for small scale radiation protection. These laws were considered rigorous in the period enacted but not anymore and can't be utilized to regulate advanced radiation systems.

3.2.2 The European regulation style

This system is synonymous with continental Europe. The safety standards in this system are set in such a way that the industry is not able to conform right away and thus considering the significant amount of time required to meet the safety standards, various kinds of exceptional provisions come into being that play as a tool to regulate the industry and conforming to the criteria becomes an incentive to the licensee. Due to the centralized way of requirement setting and supervision, government-level responsibility, rather than the responsibility of individual entity in industry, is more emphasized and in case of accident, compensation is more likely to be made by government or relevant agencies. However far from the resulting state, it is required to seek and benchmark the enforcement principle and standards to effectively achieve regulatory goals [6].

3.2.3 The U.S Regulation style

This style sets safety standards in a level that can be thought enough for most of industry to follow and the regulations and requirements that cannot possibly be accepted by the industry are not to be set. In addition, to support the industry to conform to the criteria, government provides various guidelines and expertise directly or through industrial groups and manages their quality. Oversight and supervision are performed in a limited manner but violations detected are strictly punished. This style which has a strict structure of adherence to the rule of law, has similarities with the framework of US-NRC, Britain's ONR and Republic of Korea's (NSSC) due to its strictness and adherence to the

rule of law that makes the industry comply thus maximizing protection of the environment and man. [6]

3.3 Current Kenya Regulatory Framework.

Kenya like majority of the Commonwealth borrows and models most of its political and legislation structure from the British system whose legislation base is the Anglo-Saxon/Common Law legal system. This system considers the contribution of the socio-cultural and political situation prevailing at the time in legislation.

Kenya legislated its first radiation protection law, the Radiation Protection Ordinance Act in 1948 while still a British Protectorate. This law was repealed upon the enactment of the current law, Cap 243 Laws of Kenya in 1982 and later revised in 2014. Cap 243 laws was an amended version of the 1948 Act but with additional schedules and provisions to address then advancements in technology and radiation protection standards. The Radiation Protection (Standards) Regulations, 1986 (LN54/1986) and Radiation Protection (Safety) Regulations, 2010 (LN160/2010) were further enacted to strengthen the Act. The Act and the two regulations constitute the legal and regulatory framework for safety.

Radiation Protection Board (RPB) under the Ministry of Health has grown from regulating only simple medical applications in 1948 to advanced medical, industry and research [7] as shown in figure 2 below.

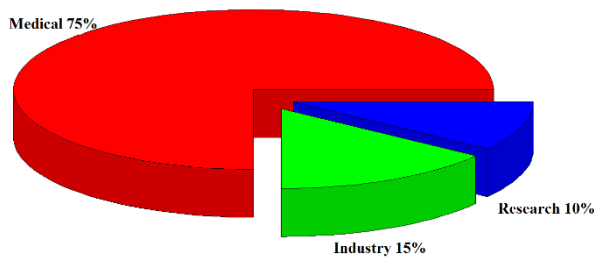


Figure 2: Sectors Currently Regulated by RPB

Although the current regulatory framework is incomplete and does not cover all aspects of GSR Part 1 Requirement 2 in environmental protection from radiation, allocation of responsibilities for safety, involvement of interested parties, provisions to appeal against any regulatory decision, criteria for release from regulatory control, preparedness and response to radiological emergencies, RPB has successfully implemented an inspectors training in enforcement and prosecution of cases that addresses non-compliance[8].

The framework however does not have provisions supporting the regulation of a radiation processing plant as none exists under its jurisdiction but with interests of additional advanced radiation technology, the government and the regulator has to take necessary steps to institute a framework that spells out and documents the national policy and strategy for safety whose implication follows a graded approach. This would

ensure that Kenya moves away from the old Commonwealth regulatory style it currently employs to the standard systems employed by its peers in radiation processing regulation and international Standards.

3.4 The comparative study of styles

This research identified that Kenya being capitalist is similar to most of continental Europe and North America, where elected representatives have the mandate to steer the direction of regulatory framework through legislation. The three should thus share most features when compared together if politics was the only base of comparison, but as figure 3 shows even with a similar political dispensation of capitalism, the framework of Kenya only share a small similarity shown by the arrow. This is can be attributed to the style of regulation where the laws are designed towards meeting an object of regulation with careful consideration on the environment where it will function, how it will function and what structures and tools will enable it to be effective.

The similarities between the American style and European style is attributed to their common goals for safety albeit with different strategies as spelled out in their national policies and the tools to be used to meet the IAEA recommendations contained in SSG-8 on safety of irradiators.

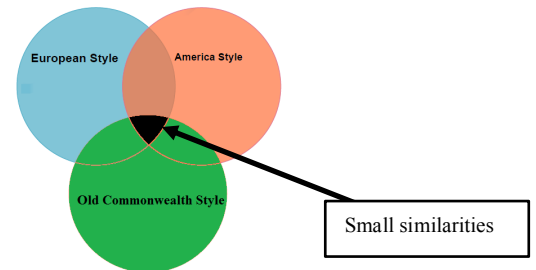


Figure 3: Style comparison

3.5 The proposed Kenya Regulation style

The proposed harmonized Kenya regulation style will ensure that safety is the key to implementation of radiation processing. This method will address the gap shown by the figure above and seek to enhance safety so that the framework can meet peer standards and recommendations from the IRRS mission to Kenya on ways to enhance safety regime. The government should thus in consultation with the regulator and experts considers this proposed approach.

The desire of any system is to achieve the higher mode of safety and security. That is why this study suggests that the proposed style be implemented in two steps. The first step involves borrowing the European style by setting standards at a level that is high and the industry players must meet, but instead of the requirements being

met immediately, it shall be a graded approach so that the industry changes from the lax style previously in store to the new system implemented in phases. However, as the ultimate goal is maximum safety, the second step, the American style, will be implemented since the industry will have already adjusted to the system but clearing out the so many leeway given to them to meet their obligations. Figure 4 below shows this distribution.

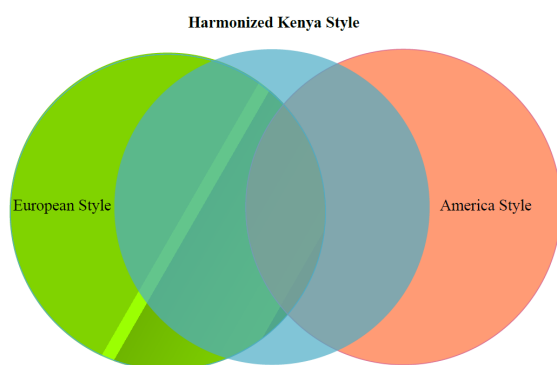


Figure 4: Harmonized Kenya Style

This is a style which borrows from the pillars of the European and American styles; namely political system, design of the law and the environment under which it will work, as well as relevant IAEA recommendations. It can be utilized in small-scaled radiation industry application countries initiating a radiation processing industry and lacking the capacity and experience to institute the stringent American style or the less-rigid European style.

In this system a country starts by following the basic standards, the regulator is not as stringent as desired by other systems and works on achieving the highest level of standards. After a specified period, the regulator moves to the next level style after evaluation. By performing this evaluation, the regulator learns from the weakness of the system and improves them so as to incorporate them into the next level step.

To ensure efficiency, the styles will not be just a copy paste, but rather the principles shall be modelled to the situation of the country while not compromising safety so as to ensure that they can be domesticated successfully. This study simulates that on successful implementation, the harmonized style will contribute to the safety culture thus enhancing the enforcement function, the monitoring functions and the licensing functions. This in turn helps the country meet the recommendations of the IAEA.

4. Conclusions

Based on the study, there is no single unified regulatory style. National regulations vary due to how the radiation processing is introduced to the legal framework and the tools (its definition; licensing

requirements, design and performance requirements, operation of the irradiators, record keeping and enforcement regime) will aid this. Some countries tend to adopt a graded approach, while others adopt a must meet strict approach.

The three regulation styles offer the following conclusions. The existing frameworks for regulating irradiators exist in multitude of legislations, codes of conduct, standard operating procedures and guidelines based on the country in question. The European style requires a considerable time for conformity by the industry, thus it offers various exceptional provisions that helps the industry conform. The American style takes a pragmatic approach of setting standards in a well thought enough level that enables industry players to comply and requirements that cannot possibly be accepted by the industry are not set. What distinguishes them from the current Kenya style is their strong foundations on ensuring safety and having effective tools to aid in that duty. Thus, the need to have the Harmonized Kenya regulation style that integrates the two systems to address the inability of the current framework to provide adequate assurance of safety and protection.

REFERENCES

- [1] IAEA, "Emerging applications of radiation Processing," *TECDOC-1386*, Vienna, 2003.
- [2] IAEA, "Enhancing the Beneficial Effects of Radiation Processing in Nanotechnology," 10 July 2018.
- [3] S. Machi, "Recent Development of Nuclear Application Technology," 2012.
- [4] J. F. a. C. Mohacsi-Farkas, "History and future of food irradiation," 2011.
- [5] M. a. Markets, "Sterilization Equipment Market by Product, Services, Consumables & End User – Global Forecast to 2021," 2016.
- [6] J. Lim, "A Review on Regulatory Enforcement Policy," *KNS Spring meeting*, 2017.
- [7] C. J. Keter, "Analysis of Radioactive Waste and Status of its Management in Kenya," *KNS 2013 spring meeting*, Kwangju, 2013.
- [8] IAEA, "IRRS Mission to Kenya," Vienna, 2016.