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A Study of Institutional Status of Risk Management for Radiotherapy in Foreign Country

Soon Sung Lee*†, Dong Oh Shin‡, Young Hoon Ji*†, Dong Wook Kim§, Sohyoun An**, Dong-Wook Park††, Gyu Suk Cho†, Kum-Bae Kim*†, Jihye Koo¶, Yoon-Jin Oh‖, Sang Hyoun Choi*†

*Radiological & Medico Oncological Sciences, University of Science and Technology, Daejeon, †Division of Medical Radiation Equipment, Korea Institute of Radiological and Medical Sciences, ‡Department of Radiation Oncology, Kyung Hee University Hospital, §Department of Radiation Oncology, ‖Research Institute of Clinical Medicine, Kyung Hee University Hospital at Gangdong, ¶Department of Bio-Convergence Engineering, Korea University, **Department of Radiation Oncology, School of Medicine, Yonsei University, Seoul, ††Department of Radiation Oncology, Inje Ilsan Paik University Hospital, Goyang, Korea

With the development in field of industry and medicine, new machines and techniques are being launched. Moreover, the complexity of the techniques is associated to an increasing risk of incident. Especially, a small error in radiotherapy can lead to a serious patient-related incident, risk management is necessary in radiotherapy in order to reduce the risk of incident. However, in field of radiotherapy, there are no legally binding clauses for risk management and there is an absence of risk management systems at an institutional level. Therefore, we analyzed institutional status of risk management, reporting & classification systems, and risk assessment & analysis in 31 countries. For risk management and reporting systems, 65% of countries investigated had legislation or regulations; however, only 35% of countries used classification systems. It was found that 43% more countries had legislation for risk management in healthcare than those for radiotherapy; 19% more countries had reporting systems for healthcare than those for radiotherapy. For classification systems, 60% more countries had legislation, recommendation, and guidelines in the field of radiotherapy than those for healthcare. Recently, international institutes have published several reports for risk management and patient safety in radiotherapy, owing to which, countries adopting risk management for radiotherapy will gradually increase. Before adopting risk management in Korea, we should precisely understand the procedures and functions of risk management, in order to increase efficiency of risk management because classification & reporting system and risk assessment & analysis are connected organically, and institutional management is needed for high quality of risk management in Korea.

Key Words: Risk management, Reporting, Classification, Proactive risk assessment, Reactive risk analysis

Introduction

In the field of healthcare, risk management refers to the management of processes and structures which effectively manage the risk of accidents that can threaten a patient's health. Risk management, which is performed to reduce the risks associated with patient safety by preventing accidents in advance, includes functions that are performed to manage a sequential process, which includes assessment and analysis, classification, and reporting of accident data.[1,2] For effective risk management, a reporting system must first be established. A reporting system provides a basis for allowing healthcare staff to easily and accurately report accidents. The reporting enables both the preparation of the solution to accidents and the prevention of the reoccurrence of accidents in the assessment and evaluation process.[3,4] A classification system, which provides a structure for classifying the data col-

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Correspondence: Sang Hyoun Choi (shchoi@kirams.re.kr)
Tel: 82-2-970-1590, Fax: 82-2-970-2412

lected by the reporting system, is used as the first step toward obtaining useful data from an accident.[5] The accident data obtained by the accident reporting and classification processes reduce the degree of danger associated with risk through the process of studying the solutions for both the accident itself and reoccurrence of accidents using risk assessment and analysis.[6]

To reduce patient-related incidents and accidents, several international organizations and institutions have published reports and papers on risk management, including the World Health Organization (WHO), European Commission (EC), European Society for Radiotherapy & Oncology (ESTRO), American Association of Physicists in Medicine (AAPM), International Commission on Radiological Protection (ICRP), and American Society for Radiation Oncology (ASTRO).[7-11] Additionally, in the international field of radiotherapy, there is an increasing awareness of the importance of risk management, and an increasing number of countries have published guidelines on radiotherapy patient safety management, including New Zealand, Canada, and the United Kingdom.[12-14] On the other hand, in the Korean medical field, the Patient Safety Act was put into effect in July, 2016 for the safety of patients and to manage risks at an institutional level; however, the legal statutes regarding radiotherapy risks were not explicit, and the provisions for managing radiotherapy accidents at an institutional level were not concrete. In addition, there has been an effort to operate a risk management system (Korea-ROSIS)[15] at Korean research organizations; however, a cooperation between individual radiotherapy organizations has not been achieved. In radiotherapy, even small errors can cause serious accidents to patients, and the types of accidents and operating systems in the field of radiotherapy are different from those in the healthcare field; therefore, there is a need for risk management techniques that are specialized for radiotherapy. In preparation for the construction of a risk management system in the Korean radiotherapy field, this research examines the radiotherapy risk management systems being operated in foreign countries and analyzes the relevant institutional status.

Materials and Methods

1. Institutional status of foreign risk management

In order to examine the institutional status of risk management, classification systems, and reporting systems in foreign countries, we analyzed 31 foreign countries, including France, the United Kingdom, and Spain. We examined whether or not risk management, reporting systems, and classification systems are being used in the fields of healthcare and radiotherapy, as well as their institutional status including legislation, regulation, recommendations, and guidelines.

2. Analysis of risk reporting and learning systems (RLS)

To determine the characteristics of reporting and learning systems (RLS) that are required to efficiently manage risk, we examined a total of 27 RLS systems being used in 13 foreign countries and three international organizations (Table 1). We

Table 1. Reporting and learning systems used across 13 countries and 3 international organizations.

Country	Reporting & Learning Systems
Australia	ARIR
Canada	AHFMR HTA ILS
Denmark	DPSD
Finland	STUK
France	Vigie radiothérapie
Ireland	IIMS
	Starweb
Italy	Incident Reporting System of Radiotherapy
	Activity in medical physics department
	Hospital Incident Reporting System
Luxembourg	CFB
Netherlands	PRISMA-RT
Spain	Radiotherapy reporting system at Hospital Clinico San Carlos
	Local system for event notification and registration in radiotherapy
	ISO 9001:2008
	Notification of Deficiencies, CSN
	Registre d'incidences ANTARES
	ROSIS
	SiNASP
Switzerland	Swiss-ROSIS
United Kingdom	ICHT/NRLS
	Datix Web
USA	JCAHO
	AHRQ WebM&M
	NRC
International organizations	SAFRON
	ROSIS
	AIMS

examined RLS system characteristics such as local/external functions, specificity, and voluntary and mandatory participation. In addition, we analyzed the characteristics, and reportable range of 14 of these RLS systems.

3. Institutional status of risk assessment and analysis

To determine the institutional status of the main functions used in risk management, including risk assessment and analysis, proactive risk assessment, and reactive risk analysis, we examined a total of 10 countries that have enacted legal statutes regarding risk assessment and analysis; the countries examined are France, Denmark, Spain, Finland, Italy, Ireland, the Netherlands, Poland, Slovakia, and the United Kingdom.

We analyzed the institutional status of risk assessment and analysis by analyzing the fields of healthcare, radiation protection, and radiotherapy, and we studied the risk assessment and analysis techniques being used in each country for proactive risk assessment and reactive risk analysis.

Results and Discussion

1. Analysis of the institutional status of foreign risk management, classification systems, and reporting systems

The results obtained after investigating the institutional status of risk management in foreign countries show that there are 17 countries which have legislation or regulations in the healthcare field, and three in the radiotherapy field (Fig. 1). In addition, five countries have recommendations on risk management in the fields of healthcare and radiotherapy, two countries have guidelines in the healthcare field, and four have guidelines in the radiotherapy field.

In terms of the institutional status of classification systems, four countries have legislation or regulations in the radiotherapy field, and seven countries have them in the healthcare field, while only eight countries have recommendations in the radiotherapy field. One country has guidelines on risk classification in the healthcare field, and five countries have guidelines on risk classification in the radiotherapy field.

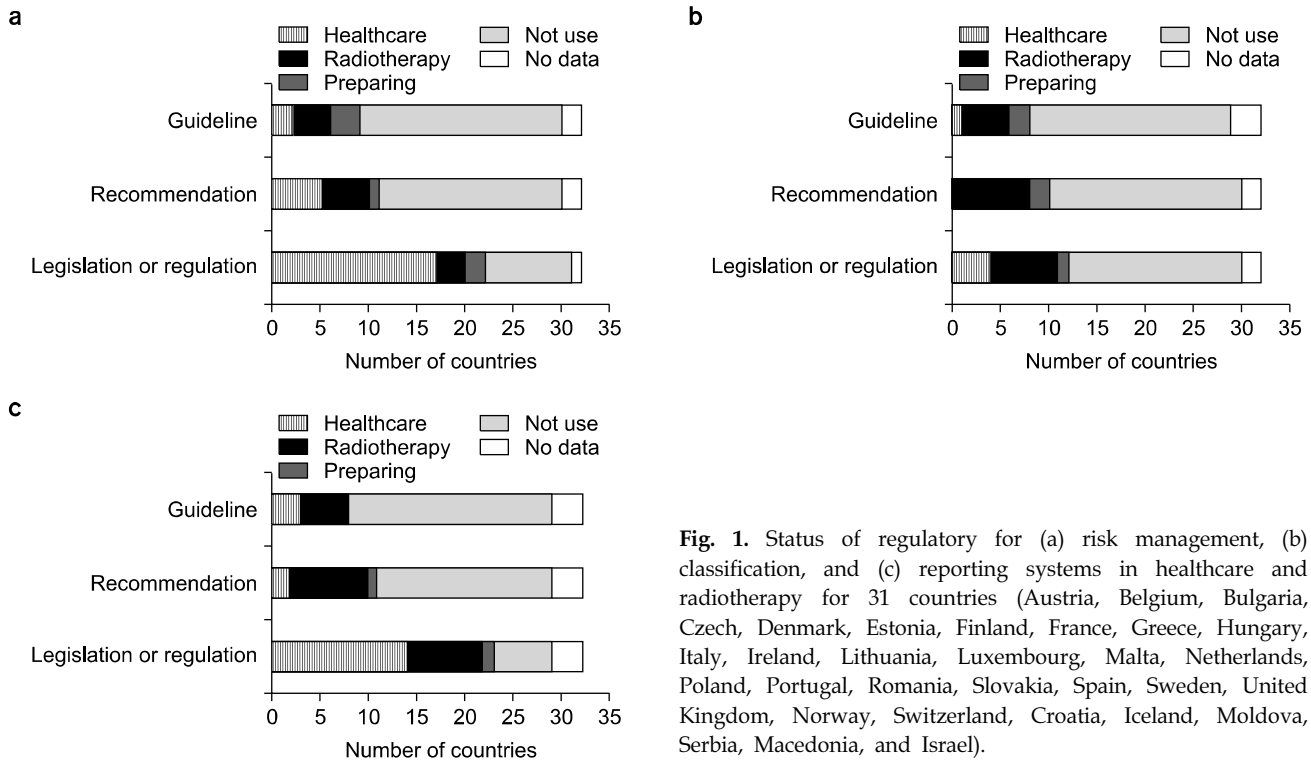

Fig. 1. Status of regulatory for (a) risk management, (b) classification, and (c) reporting systems in healthcare and radiotherapy for 31 countries (Austria, Belgium, Bulgaria, Czech, Denmark, Estonia, Finland, France, Greece, Hungary, Italy, Ireland, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Spain, Sweden, United Kingdom, Norway, Switzerland, Croatia, Iceland, Moldova, Serbia, Macedonia, and Israel).

Fourteen countries have legislations or regulations about reporting systems in the healthcare field, while eight countries have made legislations for reporting systems in the radiotherapy field. Two countries have recommendations in the healthcare field, while eight countries have them in the radiotherapy field. Additionally, three countries have guidelines for reporting systems in the healthcare field, while five countries have them in the radiotherapy field.

Over 65% of the countries have legislations on risk management or reporting systems in the fields of healthcare and radiotherapy, while only around 35% have legislations on classification systems. However, more than 60% of the countries investigated have legislations, regulations, recommendations or guidelines on classification systems in the radiotherapy field compared to the healthcare field.

In order to establish an effective reporting system, the primary task is to understand and clearly classify incidents and accidents. When incidents and accidents are reported via a reporting system, the type of accident must first be entered. Therefore, if each accident type is not defined clearly, it is impossible to operate an effective reporting system.

Among the countries that have risk management legislations, fewer than 19% of them have risk management legislations in the radiotherapy field compared to the healthcare field; however, some countries are currently making preparations, and recently, many international organizations have been publishing risk management guidelines and reports for the radiotherapy field. Therefore, the number of countries that establish risk management systems in the radiotherapy field is expected to increase gradually in the future.

2. Analysis of the characteristics of risk reporting and learning systems

Out of the 27 RLS systems, Spain had the highest with seven RLS systems, while the other countries had between one and three (Fig. 2). When the local and external functions of the RLS systems were investigated, it was found that 11 systems had local functions, seven had external functions, and nine had both functions (Fig. 3). RLS systems with local functions record accidents that occur at each institution, and this is reported to the external RLS system. External RLS systems analyze and assess accident data received from local RLS systems, classify the accidents according to degree of danger, consider methods for proactive prevention and reactive measures for the accidents, and relay these measures to the other institutions.

Fig. 4 shows the voluntary and mandatory characteristics of accident reporting systems. Out of the 13 RLS systems in the radiotherapy field, 10 are voluntary, while three are mandatory. Out of the 14 RLS systems used in the healthcare field, eight are voluntary and six are mandatory. In both fields, voluntary reporting is used more frequently than mandatory reporting; in the healthcare field, there are more mandatory reporting sys-

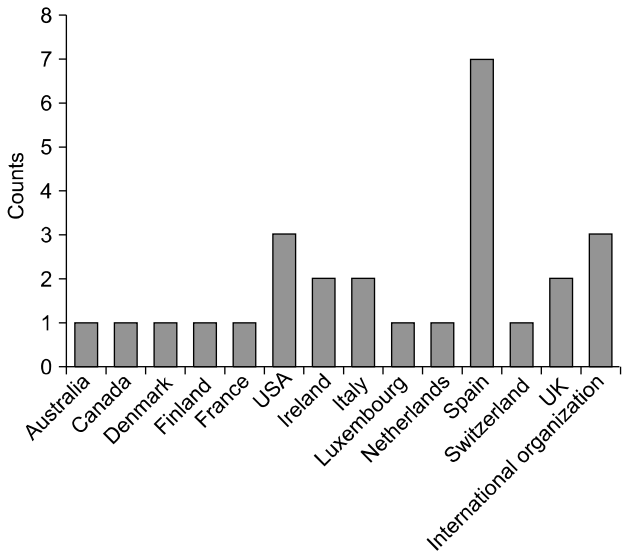

Fig. 2. Existence of reporting & learning systems by each country.

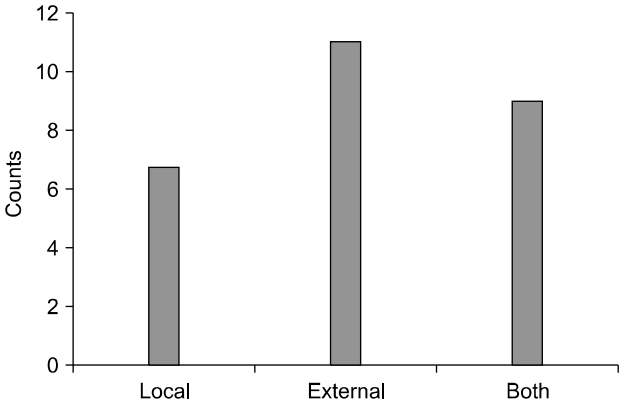

Fig. 3. Distribution of reporting & learning systems according to local and external systems.

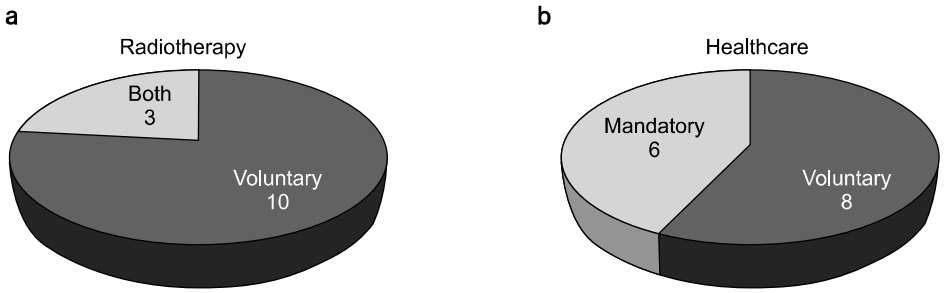

Fig. 4. Distribution of 27 reporting & learning systems for voluntary, mandatory, and both in voluntary and mandatory in radiotherapy and healthcare.

Table 2. Characteristics of 14 reporting and learning systems based on country, range of function (local/external), specificity, mandatory or not, confidentiality, and reportable range.

Name	Country	Local/External	Specificity	Voluntary/Mandatory	Reportable range
AHRQ WebM&M[16]	USA	External	Healthcare	Voluntary	All[§]
AIMS[17]	International	External	Healthcare	Voluntary	All
ARIR[18]	Australia	Both	Healthcare	Mandatory	All
Vigie radiothérapie[19]	France	External	Radiotherapy	Mandatory	All
DPSD[20]	Denmark	Both	Healthcare	Voluntary*	Adverse event
AHFMR HTA ILS[21]	Canada, Alberta	Local	Radiotherapy	Voluntary	All
JCAHO[22]	USA	External	Healthcare	Mandatory[†]	Sentinel event
NRC[23]	USA	External	Healthcare	Mandatory	Medical events (Radioactive source)
ICHT/NRLS[24]	UK	External	Healthcare	Voluntary	All
PRISMA-RT[25]	Netherlands	External	Radiotherapy	Voluntary	Near incidents
ROSIS[26]	International	External	Radiotherapy	Voluntary	Incidents/Near miss
Swiss-ROSIS[27]	Switzerland	Both	Radiotherapy	Voluntary[‡]	Incidents/Near miss
SAFRON[28]	International	Both	Radiotherapy	Voluntary	All
SiNASP[29]	Spain	Both	Healthcare	Voluntary	Adverse event Incidents Near-miss

*Mandatory only for adverse events. [†]Voluntary only for sentinel events. [‡]Mandatory only for serious events. [§]Incidents and near miss for all refer to patient safety in each field (Healthcare/Radiotherapy).

tems than in the radiotherapy field.

From among the 27 risk reporting systems currently in use, we analyzed the characteristics of 14 RLS systems being used in the United States, Australia, France, Denmark, Canada, the United Kingdom, the Netherlands, Switzerland, and Spain, as well as those being used by international organizations (Table 2).[16-29] The RLS systems being used in the United States are Agency of Healthcare Research and Quality (AHRQ) WebM&M, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and Nuclear Regulatory Commission (NRC). They are all RLS systems for the healthcare field which have external functions; NRC has mandatzory reporting, while the reporting for the others is voluntary. AIMS, ROSIS, and SAFRON are RLS systems being managed and operated by international organizations, and among these, ROSIS and SAFRON are specialized radiotherapy RLS systems that involve voluntary reporting, while AIMS is an RLS system specialized for the healthcare field which has voluntary reporting. ROSIS and AIMS have external functions, while SAFRON has both local and external functions.

DPSD and Swiss-ROSIS, which are the RLS systems of Denmark and Switzerland, respectively, have voluntary reporting of accidents. However, DPSD requires mandatory reporting of adverse events (any incident affecting patients, public or staff, include unintended injury), and Swiss-ROSIS requires mandatory reporting of serious events (an adverse event in which death or serious harm to a patient). Let us now look at the systems' reportable ranges. The United States' NRC allows

the reporting of incidents related to all radioactive sources, and the Netherlands' PRISMA-RT allows reporting of near incidents related to radiotherapy, while ROSIS and Swiss-ROSIS allow reporting of incidents and near misses. Unlike ROSIS, the Swiss-ROSIS system has both local and external functions. It uses the RO-CIRS (Radiation Oncology-Critical Incident Reporting Systems) software, the provision of which has been made to all radiotherapy-related organizations in Switzerland. RO-CIRS performs local functions, such as receiving reports on incidents and accidents within the relevant organizations, and external functions, such as assessing and analyzing the accident data reported at all organizations. In addition, it has a function which reports all incidents and accidents that occur in Switzerland to ROSIS, a central database.

3. Institutional status of proactive risk assessment and reactive risk analysis

In general, risk management has two main functions: proactive risk assessment and reactive risk analysis.

Proactive risk assessment refers to a process that helps understand and infer the range, possibility, controllability, and latent effects of the various risks which may be confronted in the future. Additionally, it has functions for proactively preventing accidents and minimizing the effects of accidents that may occur.

In the healthcare field in France and the Netherlands, proactive risk assessment is legally mandated, while in Ireland and the United Kingdom, it is mandatory in the radiation protection field. In the radiotherapy field, proactive risk assessment is mandatory in France. The assessment techniques used in proactive risk assessment include FMEA (Failure Mode and Effect Analysis), fault trees, preliminary risk analysis, and matrix probabilistic risk assessment. Moreover, some techniques are specialized for radiotherapy such as FMEA and risk matrix methodology.[30-33] France, Ireland, the Netherlands, and the United Kingdom have made legislations promoting the use of proactive risk assessment; however, there are no mandatory assessment techniques.

Reactive risk analysis refers to a process of analyzing accidents which have already occurred and identifying the causes of those accidents to prevent their reoccurrence. This process provides a basis for learning about accidents which have occurred and for creating strategies to resolve them. Reactive risk analysis is mandatory in the healthcare field in three countries: Finland, France, and Ireland. In the radiation protection field, reactive risk analysis is mandatory in Finland, France, and the United Kingdom. In the radiotherapy field, it is mandatory in Spain, Finland, and France. The main techniques used in reactive risk analysis are causal tree analysis and root cause analysis. Additionally, there is an analysis technique specialized for the radiotherapy field called HFACS (Human Factor Analysis and Classification System).[34]

Five countries including France, the United Kingdom, Spain, and Ireland have made legislations to promote the use of reactive risk analysis; however, there are no legally mandated techniques proposed in the legislations.

Proactive risk assessment and reactive risk analysis have a mutually integrated relationship in order to promote efficient risk management. By repeating the process of analyzing accidents through reactive risk analysis and studying accident prevention methods through proactive risk assessment, accident rates can be reduced and patient safety can be maximized. Among the risk assessment and analysis techniques currently in use, the number of assessment and analysis techniques specialized for radiotherapy are far lower than general techniques. Depending on the risk assessment and analysis method used, the type of risk can vary, which can cause a reduction in risk management quality. Hence, the establishment of specialized radiotherapy assessment and analysis methods is a primary challenge. Proactive risk assessment and reactive risk analysis are the main functions of risk management, and if these two functions are mutually integrated, the quality of risk reporting and classification systems can be increased.

Conclusion

In this research, we analyzed the institutional status of risk management, classification, and reporting systems as well as risk assessment and analysis in developed countries such as the United States and several European countries. In addition, we studied the characteristics of risk reporting and learning systems (RLS) that are currently in use in foreign countries. In these countries, risk management and reporting systems specialized for the radiotherapy field were insufficiently institutionalized

compared to the systems for the healthcare field. However, in the case of risk classification, more interest was shown in the radiotherapy field than the healthcare field. In addition, the results of this research show that, at present, in foreign developed countries, there is recognition of the need for risk management. There are very few countries which institutionally manage risk management systems in the radiotherapy field; however, we have seen gradual increase in the number of countries making preparations to institutionalize risk management systems.

To create an effective and efficient risk management system, type of accident and terminology must first be established, and based on this, a risk reporting system must then be established. In addition, a cyclical structure must be established for creating solution plans and prevention methods after the accident data obtained through the reporting system is assessed and analyzed. Risk management in the field of radiotherapy must be institutionally managed through this kind of sequential process. However, in order for this kind of institutionalism to fully take root and be adopted by society, we must first consider a patient safety culture, wherein the systems of cooperation between organizations regarding medical accidents are improved in addition to an improved awareness of healthcare industry staff. In order to implement highly trustworthy risk management systems for patient safety and radiotherapy in Korea, we need a precise understanding of the goals and functions of all risk management processes, and we need to establish a patient safety culture for nationwide institutional management.

References

1. ISO 31000:2009: Risk management-Principles and guidelines on implementation. International Organization for Standardization (2009)
2. Osborn S and Williams S: Seven steps to patient safety-The full reference guide. National Patient Safety Agency (2004)
3. David LC, Dubetz M, Heshmati R, et al: A Reference Guide for Learning from Incidents in Radiation Treatment. HTA Initiative #22 (2006)
4. Battles JB, Stevens DP: Adverse event reporting systems and safer healthcare. Qual Saf Health Care 18(2) (2009)
5. Ekaette EU, Lee RC, Cooke DL, et al: Risk analysis in radiation treatment -application of a new taxonomic structure. Rdiother Oncol. 80:282-287 (2006)
6. ISO/IEC 31010:2009: Risk management - Risk assessment techniques. International Organization for Standardization (2009)
7. WHO: Radiotherapy Risk Profile. World Health Organization (2008)
8. Radiation Protection N° 181: General guidelines on risk management in external beam radiotherapy. European Commission, Luxembourg (2013)
9. AAPM Task Group 100 report: Application of risk management methods to radiation therapy quality management. American Association of Physicist in Medicine (2016)
10. ICRP Publication 86: Prevention of Accidental Exposures to Patients Undergoing Radiation Therapy. Annals of the ICRP (2000)
11. ICRP Publication 112: Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies. Annals of the ICRP (2009)
12. HTA Initiative #15: Quantitative Approaches to Patient Safety - Research in Risk Analysis and Risk Management as Applied to Radiotherapy. AHFMR, Canada (2004)
13. Radiation Oncology Practice Standards New Zealand: A tripartite initiative RANZCR, AIR and ACPSEM (2013)
14. PHE-CRCE-016: Data Report on Radiotherapy Errors and Near Misses (December 2011 to November 2013). Public Health England (2014)
15. Korea-ROSIS: http://www.rosis.kr/index.asp
16. AHRQ WebM&M: http://www.webmm.ahrq.gov/ (2013)
17. AIMS: http://www.apsf.net.au/ (2000)
18. ARIR: http://www.arpansa.gov.au/radiationprotection/arir/index.cfm (2013)
19. Vigie radiothérapie: https://vigie-radiotherapie.asn.fr/ (2013)
20. DPSD: http://www.dpsd.dk/ (2007)
21. AHFMR HTA ILS: http://www.ahfmr.ab.ca/ (2007)
22. JCAHO: http://www.jointcommission.org/ (2005)
23. NRC: http://nrc.gov/ (2013)
24. ICHT/NRLS: http://www.nrls.npsa.nhs.uk/ (2003)
25. PRISMA-RT: http://www.prisma-rt.nl/ (2008)
26. ROSIS: http://www.rosis.info (2008)
27. Swiss-ROSIS: http://www.rosis.ch/ (2004)
28. SAFRON: http://rpop.iaea.org/safron/ (2012)
29. SiNASP: http://www.sinasp.es/ (2013)
30. Cantone MC, Ciocca M, Dionisi F, et al: Application of failure mode and effects analysis to treatment planning in scanned proton beam radiotherapy. Radiother Oncol. 8:127:6 (2013)
31. Scorsetti M, Signori C, Lattuada P, et al: Applying failure mode effects and criticality analysis in radiotherapy: lessons learned and perspectives of enhancement. Radiother Oncol. 94(3):367-374 (2010)
32. Ciocca M, Cantone MC, Veronese I, et al: Application of failure mode and effects analysis to intraoperative radiation therapy using mobile electron linear accelerators. Int J Radiat Oncol Biol Phys. 82(2):305-311 (2011)
33. Vilaraqut JJ, Duménigo C, Delgado JM, et al: Prevention of accidental exposure in radiotherapy: the risk matrix approach. Health Phys. 104(2):139-150 (2013)
34. Portaluri M, Fucilli FI, Bambace S, et al: Incidents analysis in radiation therapy: application of the human factors analysis and classification system. Ann Ist Super Sanita. 45(2):128-133 (2009)