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## How safe is radiotherapy practice in India: perceptions and practical experiences among the workers of radiotherapy facilities in North East, India?

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#### Abstract

Purpose: The aim of this study was to understand how the regulatory requirements for functioning radiotherapy practices in India to control risk were conceptualised, perceived and applied accordingly in the radiotherapy facilities. It further examined how the social factors influenced the decision-making process for implementing regulatory requirements in the radiotherapy facilities. Material and method: This study was carried out in nine radiotherapy facilities located in the northeastern Indian states of Manipur, Assam, Meghalaya, Tripura and Mizoram. The study adopted both the semi-structured and in-depth questionnaire, developed on the basis of multidisciplinary fields. Result: The study found that the facilities in the northeastern regions were commissioned in line with the regulatory requirements. The facilities had adequate structural shielding rooms to protect workers, patients and the public from the risk of ionising radiation. However, in the operational phase of the facilities, majority of the facilities had the improper management of existing resources and nonimplementation of regulatory requirements on time. It was observed that workers in some facilities continued the practice, despite the failure of specific safety functions, or not meeting regulatory requirements. Such practices led to the suspension of patient treatment in three of the facilities by the regulator. The existence of a varying nature of risk perceptions among oncologists, medical physicists, radiological safety officers, radiotherapy technologists in the facilities were observed and these influenced the decision-making process of the facilities on the implementation of regulatory requirements. Conclusion: The study found that the facilities needed to explore various means, including to narrow the gap that existed in respects of perceived risk (within the facilities), communication to enhance work coordination and mutual trust among workers. The adoption of the institutional policy for conducting an internal audit of working practices, encouragement of workers to participate in continuing education programs would enhance effective utilisation of already existing infrastructure/ equipment and work procedures including quality assurance programs.

#### Introduction

There is a rise in the number of radiotherapy facilities in India for the treatment of cancer. These facilities are regulated by the Atomic Energy Regulatory Board (AERB), India. One of the primary objectives of this regulation is to protect the health of individuals, and the environment from the risk of use of ionising radiations in the facilities. AERB considers this 'risk' in line with the glossary of International Atomic Energy Agency as 'A multi-attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with an actual or potential event under consideration. It relates to quantities such as the probability that the specific event may occur and the magnitude and character of the consequences'.<sup>1,2</sup> To achieve the goal of radiological protection from such risk, AERB regulates the facilities through the enforcement of regulatory requirements. The following establish these regulatory requirements:

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- Atomic Energy Act 1962<sup>3</sup>
- Atomic Energy (Radiation Protection) Rule 2004<sup>4</sup>
- Surveillance procedures for medical application of radiation 1989<sup>5</sup>
- Safety code on radiation therapy sources, equipment and installations<sup>6</sup>
- Safety code on safe transport of radioactive material<sup>7</sup>
- Testing and classification of sealed radioactive sources<sup>8</sup>

- Safety guide on security of radioactive sources in radiation facilities<sup>9</sup> and
- Safety guide on security of radioactive material during transport<sup>10</sup>

It is the responsibility of facilities to establish the radiological protection systems according to the regulatory requirements of AERB.

Although the radiotherapy practice in India is more than five decades old, there is still limited availability of literature on the establishment of radiological protection systems. Further, a lack of data on radiotherapy incidents in Asian countries has been reported elsewhere.<sup>11</sup> The studies in other countries found that radiotherapy practice, sometimes, experienced the risk of recurrence of tumour, toxicity and even fatalities among the patients, who received incorrect dose.<sup>12–16</sup> Also, it has been reported about the incidences of overexposure, radiation injuries and even death among workers in some facilities.<sup>17</sup> Sir Liam Donalson, Chair, World Alliance for Patient Safety also observed radiotherapy practice as 'Radiotherapy is widely known to be one of the safest areas of modern medicine, yet, for some, this essential treatment can bring harm, personal tragedy and even death'.<sup>11</sup>

It was found that risk of incidents occurring in radiotherapy was associated with the lack of communication, lack of technical skill, working practices of the workers, ignorance of safety warnings and risk perception of management and their pressure on the continuation of works despite failure in safety systems.<sup>13,14,18</sup> Further, the available literature in radiotherapy practices did not reveal in detail about the influence of social factors (SF) on defining risk and decision-making processes in the implementation of regulatory requirements. Many researchers mainly from the social sciences, found that SF like risk perception, attitude, working behaviour, work coordination, communication, hierarchy and work pressure played a vital role in shaping the same physical risk, and played a significant role in the decisionmaking processes for implementation of regulatory require-ments.<sup>19-31</sup> It was found that the physical risk, defined by natural scientists underwent attenuation and amplification according to risk perception, communication and political interest. Barke et al.<sup>32</sup> also found that even the scientist exhibited different risk perceptions on the same physical event. Interestingly, they observed that scientists in the same discipline had different perceptions according to demographic factors. In other studies, Branden<sup>33</sup> found the shaping of risk by the risk perception of the institution and scientists based on their political interests. Many individuals, including technical experts, exercised risk perception and heuristic approaches for the immediate assessment of risk, even though it led to severe errors in the estimated risk.<sup>34,35</sup>

The present study attempted to understand how SF influenced the implementation of regulatory requirements for establishing radiological protection systems in facilities located in North Eastern (NE) India. Further, it also attempted to examine the nature of the risk being experienced in the facilities. The multidisciplinary risk assessment approach was adopted in this study. In this study, facility shall mean radiotherapy facility. It may be a part of the institution, having multidisciplinary facilities or a facility solely dedicated to the treatment of cancer patients. Equipment shall mean equipment that generates ionising radiation, such as teletherapy machines, brachytherapy machines, simulators and computed tomography. The actors shall mean regulator, manufacturer of equipment, supplier of equipment, the employer, and administrator of facility and workers. The regulator shall mean AERB, Government of India. The administrator shall mean staffs assisting the employer in the administration of the facility. The worker shall mean radiation oncologist, radiological safety officer (RSO), medical physicist and radiotherapy technologist.

#### **Materials and Method**

#### Study site

The study was carried out in nine radiotherapy facilities located in Imphal (Manipur), Dibrugarh (Assam), Guwahati (Assam), Jorabat (Assam), Silchar (Assam), Shillong (Meghalaya), Agartala (Tripura) and Aizwal (Mizoram) of NE States, India. The average distance among the facilities was within the range 10–1,000 km. Assam has the maximum number of facilities in the region. It has six facilities, out of which three facilities were government institutes, one facility was autonomous institute and the remaining two facilities were private institutes. There was only one facility in each of the states of Manipur, Meghalaya, Mizoram and Tripura. These nine facilities were selected from out of 13 facilities available in the entire NE India, based on a minimum of 3 years of experience in the treatment of patients. Further, selections of facilities in NE states were based on the following factors:

- Far from the headquarter of AERB, Mumbai: The facilities were located about 2,000–3,000 km away from the headquarter of AERB, Mumbai.
- Non-availability of service provider, supplier of equipment in the region and
- Socio-political instability of region due to frequent general strikes and blocking of the normal functioning of offices and militant conflict.<sup>36–38</sup>

#### Method

The conceptual framework used in this study is shown in Figure 1. This framework consists of three parts: radiological protective systems (RPS), regulatory system and SF. The RPS is to be established in the facilities as per the regulatory system of India.<sup>3–10,39</sup> The components of RPS covered in the present study are shown in Figure 1. The second part, the regulatory system as shown in Figure 1 consists of three components, which are used as a tool by AERB for regulating the facilities.<sup>3-10,39</sup> The study considered that the establishment of radiological protection systems in conformity with the requirements of the regulatory system primarily protected the worker, patient and public from the risks associated with the use of ionising radiations. The existence of the components of RPS and regulatory system in the facilities were assessed using a semi-structured questionnaire (Table 1). This questionnaire was derived from literature reviews on the regulatory system of India, IAEA safety standards/guides, and radiotherapy accidents.<sup>4,13,39-41</sup>

The SF, the third part of this framework, is used to understand how the RPS and the regulatory system change under the influences of SF. The components considered are shown in Figure 1. These include perceived risk, communication of risk, working behaviour, attitude, work pressure, work coordination and hierarchy. Perceived risk is further considered as a function of knowledge, experience, trust and demography. These terms are explained in the literature elsewhere.<sup>19–30,42</sup> An in-depth



\* RP & DI Instruments = Radiation protection and dosimetric instruments

Figure 1. Conceptual framework for the assessment of radiological protection systems in radiotherapy facilities. RP and DI instruments, radiation production and dosimetric instruments.

interview questionnaire was developed based on the above literature. The contents of the questionnaire are provided in Table 1. To minimise the influence of the contents of the questionnaire on the response of the workers, interviews of the workers started with the questions: the thoughts and images that came to their mind when they heard the word 'radiation', followed by their risk perception on radiation before and after working in the radiotherapy facility. The study interviewed 45 workers. They were selected from the 88 workers, which were registered with the regulator. Five workers were selected from each facility. They included a radiation oncologist, RSO, medical physicist and radiotherapy technologist. In some facilities, the medical physicist also served as RSO. In total, the researcher interviewed nine radiation oncologists, nine RSO, nine medical physicists and 18 radiotherapy technologists for this study.

#### Results

The status of facilities regarding the availability of equipment, workers, patient workload and treatment modalities are given in Table 2. The total number of workers in nine facilities was 88 comprising of radiation oncologists, RSO, medical physicists and radiotherapy technologists. The number of medical physicists was the lowest in the facilities as compared with another category of workers. It was due to the recruitment of a minimum number of medical physicists required in the initial functioning of the facility as per regulatory requirements, and inordinate delays in the decision-making process for updating the requirements after initial recruitment. In a facility having only one medical physicist, the dual functions of medical physicist and RSO were carried out by a single medical physicist. However, in one facility, more than two medical physicists served as medical physicist cum RSO. Employing more than two RSO in the same facility was not to paralyse the duties of the RSO, instead to share the assigned duties if the need arises.

Regarding the gender distribution among facilities, there were a lesser number of women in the profession of radiotherapy practice, constituting only 13.6% (12 women workers) of the total workers. The number of women radiation oncologists was four, and they were found to be working in three facilities only. There was only one woman medical physicists found to be working. The remaining seven women workers were radiotherapy technologists, having less than 6 years of working experience in the facilities.

The educational qualifications of these workers were in accordance with the requirements mentioned in the AERB safety Code.<sup>6</sup> The radiation oncologists held a postgraduate degree in radiation therapy/radiation oncology. Some of the oncologists had more than 20 years of working experience in the field. The medical physicists held Diploma in radiological or medical physics, after a postgraduation in science. In addition to the required educational requirements, two medical physicists held a Ph.D. degree. The RSO in the facilities were the medical physicists, approved by the competent authority of the regulator. The radiotherapy technologists had a graduate degree in science as educational background, followed by a 2-year course in radiation therapy technology.

The workers had familiarisation with the AERB and the majority of them accessed its website for updating knowledge of regulatory requirements. They were aware of the use of personal monitoring devices (PMD) during work procedures. In India, the annual permissible dose limit for the worker is 20 mSv averaged over 5 years, and 30 mSv is the maximum annual permissible dose limit. The workers were aware of these limits.

#### Table 1. Contents of the questionnaire

Part A							
Q. What are the imaginations coming in your mind immediately when the word RADIATION is mentioned? (Hint: Please write any images such as Atomic weapons, war,Electricity, Clean Environment, Healthcare,coming to mind) <sup>30</sup>							
Q. What did you feel when you entered a radiation room for the first time in your life? Please share your perceptions and experience about risk							
Q. What do your co-workers feel about the risk of working in your facility? How do they practice to achieve radiological protection in your facility? What do you feel about risk in radiotherapy after working in this field? Please share your perceptions and experience about risk							
Q. What is the culture of visiting the website of Atomic Energy Regulatory Board (AERB), reading the publication of AERB on a regular basis in your facility? What is the 'Level of familiarisation of particular act/rules/code which applies to your practice' among your co-workers?							
Q. Do you read publications of International Atomic Energy Agency (IAEA), United Nations Scientific Committee on Effects of Atomic Radiation and International Commission on Radiological Protection (ICRP) to upgrade knowledge in your field? <sup>30</sup> If yes, how do you access these publications?							
Q. Do you agree that it is necessary to replace radiation practices by alternative means? If no/yes, why?							
Q Do you agree, 'If no health problems were detected in the last 25 years while working in radiation practice without wearing TLD and appropriate radiation protective equipment, we need not use them further'? Do you observe that some of your co-workers/employer/policymaker have such perceptions, conceptions and apply accordingly? <sup>30</sup> Please share your experience in details							
Q. Do you think, 'Decision on risk is influenced by socio-economic and political influence"? <sup>30</sup> Please share your experience							
Q. Do you think that management systems of your institute are adequate to protect worker and patients from the risk associated with your practice? If no, please provide your suggestions for improvement?							
Q. How do your employer/administrator react if any lapses in radiological protection system are detected? Do you think your employer/administrator will inform the regulatory body? Please explain how in either case. Can you inform the regulator directly about the violation of regulatory requirement or unavailability of radiological protection systems in your facility? If yes/ no, please express your opinions <sup>30</sup>							
Q. How would the majority of your co-workers behave if radiation accident takes place in other facility/institution? Please explain <sup>30</sup>							
Q. Do you agree that if radiation accident takes place in other facility/institution, your employer/policymaker would try to implement the lessons learned from that accident to prevent similar types of accidents in your facility? Please explain how in either case <sup>30</sup>							
Q. What do your co-workers behave if any procedural error committed? Will they intimate to employer or regulator? Explain how in either case <sup>30</sup>							
Q. What did you experience about the effects of hierarchy, work pressure, work coordination and communication in discharging your practice? Do you think your co-workers, too, experience similar effects? Please share your experience							
Part B							
Q. When did your facility start treatment of cancer patients using radiations?							
Q. What are the radiation-generating equipment available in your facility?							
Q. What are the patient treatment modalities available in your facility? Do you use computerised treatment planning system?							
Q. How many patients are treated per annum?							
Q. How many radiation oncologists, radiological safety officer, medical physicist and radiotherapy technicians are in your facility? What is the distribution of gender among these workers?							
Q. What are your educational backgrounds for working in the present facility? Do you acquire additional training programme?							
Q. What are the areas in which you find difficulty in the implementation of regulatory requirements? Why do you face difficulties in such areas?							
Q. Do your facility carry out quality assurance of equipment on a routine basis? If no, why?							
Q. Do your facility conduct the meetings on radiological safety? Do you participate in it? If no, why?							
Q How do you maintain the records of the personal monitoring device, quality assurance of equipment, servicing and maintenance of equipment?							
Q Have you ever seen sharing of the same personal monitoring device (PMD) among the workers? If yes, why do they share PMD? Did employer take action against them for sharing PMD?							
Q. Do you think your co-workers use personal dose monitoring devices during working in radiation field? If no, why they are not using PMD?							
Q. Do you calibrate the radiation protection and dosimetric instruments on time before the due date of calibration? If no, why? What are perceptions of your co-workers using such expired instruments?							
Q. Do you continue treatment of patients even though the failure of specific safety components or non-implementation of regulatory requirements in the facilities? If yes, why do you continue? How do you perceive risk in such scenarios?							
Q. Have you ever faced suspension of patients treatment by the regulator?							

#### Table 2. Status of radiotherapy facilities in North East, India

				No. of workers				
Centres	Type of organisation	No. of years of functioning	Types of equipment	Radiation oncologist	Medical physicist	Radiotherapy technologist	Approximately no. of patients treated annually	Treatment options
A	Government	> 15	1-Telecobalt unit 1-Brachytherapy unit	4	2	3	590	Conventional
В	Government	> 35	1-Telecobalt unit 1-Brachytherapy unit	1	2	4	700	Conventional
С	Government	> 10	1-Telecobalt unit	2	1	4	700	Conventional
D	Government	> 30	2-Telecobalt units 1-Brachytherapy unit	5	2	4	1,100	Conventional
Е	Government	> 10	1-Telecobalt unit	1	1	2	250	Conventional
F	Government	> 20	1-Telecobalt unit 1-Brachytherapy unit 1- Simulator	5	2	4	600	Conventional
G	Autonomous	> 35	2-Telecobalt units 3-Medical Accelerator units 1-Brachytherapy unit 1-CT simulator 1-Simulator	5	5ª	16	3,000	3-Dimensional conformal radiotherapy (3-DCRT), intensity modulated radiotherapy (IMRT), conventional
Н	Private	> 5	1- Medical Accelerator unit 1-Brachytherapy unit 1-CT simulator	2	2	2	600	3-dimensional conformal radiotherapy (3-DCRT)
I	Private	>5	1-Telecobalt unit 1-Brachytherapy unit	1	2	3	300	Conventional

Note:

<sup>a</sup>In addition to medical physicist registered with AERB, the facility has trainee medical physicists.

It was observed that the workers had the perception that the societal benefits of radiation, in particular to the healthcare sector was more than the risks likely to be encountered during practice. They felt that such practice would continue to expand through the development of new technologies. The workers perceived that the risk associated with radiotherapy practice could be controlled through inherent safety measures and proper operational measures. The women workers, mainly technologists, showed higher levels of concern than the male worker. However, the women and male radiation oncologists exhibited similar risk perception.

Many workers, mainly from radiation oncologist and medical physicist, were also involved in research and development activities in addition to their routine duties of patient treatment. However, it appeared that the majority of workers made little effort to update their knowledge through regular reading of publications of AERB, IAEA, ICRP and UNSCEAR. However, the workers exhibited the desire for participating in training programs, workshops and seminars to upgrade their knowledge and technical skill. They had a high-risk perception in the operation of equipment without proper training, because of the increasing complexity nature of the operating systems of the equipment. However, many workers experienced difficulties in accessing training programme. A worker narrated his experience as:

In many cases, our request for participating continuing education programs was turned down on the grounds of nonavailability of funds. They believed that such continuing education program was not required as there was no high risk in this practice as compared to another medical department in the facility. Our employers also do not pay much interest in making policy for continuous upgrade of technical skill of the worker.

All the facilities had adequate structural shielding of rooms, where radiation sources were being installed (Figure 2). The facilities constructed these rooms in line with regulatory requirements of AERB, and there was no any modification of rooms against the AERB approved layout plan. The dose rates in the respective areas around the shielded rooms were measured using a survey metre, and it was observed that radiation dose rates were below the limits prescribed by AERB. Thus, the primary



Figure 2. Status of radiological protection systems established under the regulatory system of India among nine radiotherapy facilities located in North Eastern States, India.

protection of workers and the public from the risk of operating radiation source were achieved through the structural shielding of the rooms. The other operational safety feature found in the facilities were adequately functioning of an emergency switch on the control panel, door interlock system, patient viewing system and availability of T-rods in the rooms having teletherapy source.

The study found that many facilities did not calibrate radiation monitoring instruments as often as is recommended (Figure 2). Such instruments included survey metre, area zone monitor to be used in teletherapy and brachytherapy room, electrometer and secondary standard dosimeter. The non-functioning of gamma zone monitor installed in one teletherapy room was observed.

Other radiological safety problems encountered in many facilities were the non-availability of PMD, non-replacement of PMD on time, use of other worker's PMD and improper storage of PMD. The new workers mainly used PMD of other workers. A worker narrated his experience in working without a radiation monitor as:

When I first noticed the non-functioning of area zone monitor, I was scared to enter the room because of risk involved in it. At that time, calibration due date of survey meters expired. Further, I had no PMD and used someone's PMD. I intimated the matter to the RSO. However, the RSO needed to take advice from the higher authority of Institute before making a decision. Finally, I was instructed to continue the service. Fearing the security of my job, I continued to practice more than one month.

A senior radiation oncologist having more than 20 years of working experience in the radiotherapy facility expressed his experience in the lack of implementation of the regulatory system as follows:

We are unable to get new personal monitoring devices (PMD) on time, as the institute do not pay fees for PMD to the service provider, and hence, we are working without PMD. We have experienced suspension of treatment of patients in the facility by the regulator for violation of regulatory requirements. After the regulatory action, the institute took the initiative to implement the regulatory requirements.

The workers in two facilities also experienced similar regulatory actions. Many workers perceived that the quality assurance of the treatment units and equipment were not carried out on a routine basis and there was poor maintenance of record keeping. A worker expressed his experience in this regard as:

I feel that our facility initiated implementation of quality assurance programs in line with regulatory requirements after regulatory inspection. Earlier, it was not done on a periodic basis. Some workers feel that performance characteristics of the equipment do not frequently change as evident from their past working experience, and hence there may not be a need to doing all the quality assurance procedures on time.

A typical experience found among the workers was about the difficulties encountered during the downtime of equipment, as there was no service provider in the NE region. In some facilities, downtime of equipment continued for a week. Such downtime affected the treatment schedule of the patients, and many patients left the facility to access treatment in the other facility. In emergency preparedness, it was observed that the majority of workers had a low-risk perception about the non-availability of the display of emergency procedures. In some facilities, although emergency response planning was displayed, mock drills were not conducted as a part of preparing for an emergency response.

In many facilities, it was observed that the workers holding the lower grade post had to follow the existing working procedure due to the hierarchy effect. Due to this effect, sometimes they had to continue the practice, even in the failure of a particular safety component or violation of the regulatory requirements. Although such cases were situational and temporary, it increased anxiety and worry levels among the workers. Although the facilities were located in an unstable socio-political region, the facilities were open during the general strikes or any other social unstable situations and did not interrupted the treatment schedule of hospital-based patients. However, it mostly affected the patients who travelled into the facility. The workers experienced a prolonged interruption in the treatment schedule of outdoor patients and increased anxiety levels among the patients. The workers also did not experience any undesirable threat to the treatment room or during the transportation of radioactive material.

The facilities were found to communicate regularly with the regulator. The communications were mainly between the RSO of

facilities and the regulator. With the introduction of an online licensing system called e-licensing of radiation applications by the regulator in the last 4 years, communication between facilities and the regulator are on the rise. In addition to this communication, the regulator inspected the facilities physically once every 3–5 years.<sup>39</sup>

#### Discussion

The facilities in NE India had the necessary regulatory infrastructure such as adequate structural shielding rooms, qualified workers, monitoring instruments and quality assurance tools. However, the majority of facilities had the improper management of available resources and improper implementation of regulatory requirements on time. The existence of the required infrastructure alone is not enough to ensure an adequate level of radiological protection systems in facilities, as evident from some accidents that have occurred in facilities elsewhere.<sup>13,14,18</sup>

The majority of facilities made little effort in use of PMD, survey metre, gamma zone monitor and keeping monitoring records. The use of expired monitoring instruments, sharing of other worker's PMD and working in a telecobalt room without a gamma zone monitor pose a threat to achieving radiological protection. Such a practice is also a violation of the regulatory requirements. It was observed that the workers, although aware of such risk, continued the malpractices in some facilities. The continuation of such practice could introduce severe errors and mistakes in the assessment of dose received by the workers. Ortiz, P et al. (2002) also found that many radiation accidents were associated with ignorance of failure of safety warning systems and overconfidence. It is also reported that consistent neglect of regular follows up of equipment malfunction, and continuation of unsafe working practices led to the accidents.<sup>13,14,18</sup>

Another major issue observed in the facilities was the lack of management of quality assurance programs. Quality assurance of the equipment is required to ensure that the system works as per design specification of the equipment and it assures accurate delivery of the prescribed radiation dose to a tumour effectively without exceeding the tolerance dose of surrounding normal tissues.<sup>43</sup> It also provides safety for the workers. It has been reported that the lack of quality assurance caused more than 60% of radiotherapy accidents.<sup>44</sup> The facilities needed to adopt carrying out of quality assurance measures on a routine basis and ensure proper maintenance of its records. Such adoption could enhance the prevention of any incidents/errors likely to be encountered.<sup>45</sup>

The reasons why the working practices in the facilities deviated from the regulatory requirements are sometimes intertwined among the actors involved in this practice. It was observed that the facilities tended to continue violation of the regulatory requirements, despite experiencing actions by the regulator. The majority of workers were aware of the physical risks associated with working in a radiotherapy facility having weak radiological protection systems. However, the control of such risk at the individual level was constrained by many factors such as work procedures, teamwork, work coordination, trust, communication and support from the employer.

A hierarchy system and working pressure could be a tool adopted by the institute to execute the functions of the institute to achieve their targets. However, such a system could cause pressure on the workers at lower hierarchy levels.<sup>46,47</sup> Some workers

in the facilities experienced the adverse effect of such hierarchical systems, when they were asked to work despite lack of safety functions and violations of the regulatory requirements. The workers felt unable to communicate this non-compliance to the regulator, because of possible action against them by the employer. The institute was also unlikely to report such incidents, fearing regulatory action against them and loss of reputation of the institute. It could be one of the reasons for lack of reported incidents in radiotherapy, mainly of patients receiving the incorrect doses. Work pressure experienced by some workers was another factor, which could contribute to causing an error in the work procedure and violation of regulatory requirements on a situational basis.<sup>24</sup>

There were different risk perceptions among the workers for implementation of radiological protection systems and other regulatory requirements in the facilities. Such different perceptions led to a polarisation of workers in favour versus against the implementation of radiological protection systems in the facility. The workers who adopted risky decision-making based on their previous work practice attempted to continue the practice, even though it violated regulatory requirements. The existence of such polarisation among the workers also affected the decision-making process in the establishments of radiological protection systems. Thus, the risk experienced was not only limited to the physical risk, but it was also about the perceived risk involved in deciding to continue the practice during the failure of radiological protection systems or violation of regulatory requirements. In these circumstances sometimes the decision was taken at higher administrative levels, based on subjective judgement.

The workers felt that the staffs in the administrative levels were not aware of the risk associated with ionising radiation. They tended to judge the radiotherapy practice as low risk in comparison with other medical practices, evident from the nonoccurrence of radiation injuries and fatalities among workers and patients. Such risk perceptions posed a barrier to establishing radiological protection systems in the facilities and enhanced risk among workers and patients.

The consistent ignorance of safety recommendations of workers by the employer was a typical experience in facilities. In many instances it was perceived that too much time was required to implement safety measures and therefore, malpractices continued until intervened by the regulator. If the facility was required to stop the treatment, due to either intervention by the regulator or failure of components of equipment, the facility remained closed for many days. It affected the patients, as there was an insufficient number of facilities in the regions and because of poor road connectivity in the majority of these hill regions, patients also could not reach other facilities for the continuation of treatment.

#### Conclusion

The facilities in the NE regions were established in line with the regulatory requirements. The facilities had adequate structural shielding rooms to protect the worker and the public from the undue risk of ionisation radiation. They also had the workers whose educational qualifications were in line with the regulatory requirements. The workers had a positive attitude toward the use of ionising radiation for treatment of cancer. However, it was observed that the majority of workers was engaged in risky working behaviours such as the use of expired PMD, use of other

worker's PMD, improper storage of PMD, use of expired survey metres, area monitors, electrometers and not performing quality assurance procedures on a routine basis.

The study also observed the existence of a varying nature of risk perceptions among the various actors in the facilities and this influenced the decision-making process of the facilities for practicing radiotherapy in accordance with regulatory requirements. Such working conditions are likely to increase the risk of delivering an incorrect radiation dose. It may also cause risk to workers in the occurrence of incidents/accidents in the facilities. Some workers were not worried about such working conditions due to their long-term experience of receiving a permissible dose well below the annual permissible dose limit set by the regulator, and also, non-occurrence of radiation injuries or fatalities in the facilities. The workers who had high-risk perceptions about such working scenarios, also appeared to continue risky working behaviours. This may be due to many factors like hierarchy effect, work pressure and involvement of teamwork in controlling risk.

The study found that the facilities need to explore various means including narrowing the gap that existed in respect of perceived risk (within the facilities), communication between the facility and the regulator and to enhance work coordination and trust among workers. The adoption of an institutional policy for conducting an internal audit of the work practices, encouragement of workers to participate in continuing education programs could enhance effective utilisation of already existing infrastructure/equipment and work procedures including quality assurance programs. The study suggests to include SF such as risk perception, communication and behaviour of workers in the risk assessment approach of the facilities, and prescriptive approach of the regulator, which are to be used in the regulatory inspection of facilities.

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Conflicts of interest. There is no conflicts of interest.

**Ethical standards.** The author took prior consents from all the participants for the study. They were informed in advance that they have the right to withdraw their participation at any time during the fieldwork, and not to answer the questions, which would be against their personal/institute's interest. The author agreed that collected data would be used for the academic purpose, and would not reveal the name of the participants and their institutes.

#### References

- International Atomic Energy Agency. Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection, 2007 edition. Vienna: International Atomic Energy Agency, 2007.
- Atomic Energy Regulatory Board. Glossary of Terms for Nuclear and Radiation Safety, Guide No. AERB/SG/GLO. Mumbai: Atomic Energy Regulatory Board, 2005.

- Atomic Energy Act 1962. http://dae.nic.in/?q=node/153. Accessed on 12<sup>th</sup> May 2017.
- Atomic Energy (Radiation Protection) Rules 2004. Published in the Gazette of India: 11 September 2004] Part –II, Section 3, Sub-Section (i). http://dae.nic.in/writereaddata/RPR2004.pdf. Accessed on 12<sup>th</sup> May 2017.
- Atomic Energy Regulatory Board. Surveillance Procedures for Medical Application of Radiation 1989. Mumbai: Atomic Energy Regulatory Board, 2005.
- Atomic Energy Regulatory Board. Safety Code on Radiation Therapy Sources, Equipment, and Installations, AERB/RF-MED/SC-1 (Rev.1). Mumbai: Atomic Energy Regulatory Board, 2011.
- Atomic Energy Regulatory Board. Safety Code on Safe Transport of Radioactive Material, AERB/NRF-TS/SC-1 (Rev.1). Mumbai: Atomic Energy Regulatory Board, 2016.
- Atomic Energy Regulatory Board. Testing and Classification of Sealed Radioactive Sources, AERB/SS/3 (Rev.1). Mumbai: Atomic Energy Regulatory Board, 2001.
- 9. Atomic Energy Regulatory Board. Safety Guide on Security of Radioactive Sources in Radiation Facilities, AERB/RF-RS/SG-1. Mumbai: Atomic Energy Regulatory Board, 2011.
- Atomic Energy Regulatory Board. Safety Guide on Security of Radioactive Material During Transport, AERB/NRF-TS/SG-10. Mumbai: Atomic Energy Regulatory Board, 2008.
- World Health Organisation. Radiotherapy risk profile. http://www.who. int/patientsafety/activities/technical/radiotherapy\_risk\_profile.pdf. Accessed on 21<sup>st</sup> May 2017.
- Chang D W, Cheetham L, te Marvelde L et al. Risk factors for radiotherapy incidents and impact of an online electronic reporting system. Radiother Oncol 2014; 112 (2): 199–204.
- International Atomic Energy Agency. Lessons Learned From Accidental Exposures in Radiotherapy, Safety Reports Series No. 17. Vienna: International Atomic Energy Agency, 2000.
- International Commission on Radiological Protection. Prevention of Accidents to Patients Undergoing Radiation Therapy. ICRP Publication 86. Annals of ICRP 30(3). Oxford: Pergamon Press, 2000.
- 15. Ortiz P, Oresegun M, Wheatley J. Lessons from major radiation accidents. Proceedings of the 10th International Congress of the International Radiation Protection Association, 14<sup>th</sup>–19<sup>th</sup> May, Hiroshima 2000. http:// www.irpa.net/irpa10/cdrom/00140.pdf. Accessed on 15<sup>th</sup> May 2017.
- Stavem P, Brøgger A, Devik F et al. Lethal acute gamma radiation accident at Kjeller, Norway: Report of a case. Acta Radiol Oncol 1985; 24 (1): 61–63.
- International Atomic Energy Agency (IAEA). Lessons Learned from the Response to Radiation Emergencies (1945–2000). Vienna: International Atomic Energy Agency (IAEA), 2012.
- Nénot J C. Radiation accidents over the last 60 years. J Radiol Prot 2009; 29 (3): 301.
- Covello V T, Slovic P, Von Winterfeldt D. Risk Communication: A Review of the Literature. Risk Abstracts 1986; 3 (4): 172–182.
- 20. Mary D. Risk Acceptability According to the Social Sciences. New York: Russell Sage Foundation, 1986.
- Freudenburg W R. Perceived risk, real risk: social science and the art of probabilistic risk assessment. Science 1988; 242 (4875): 44–49.
- 22. Gregory R, Mendelsohn R. Perceived risk, dread, and benefits. Risk Anal 1993; 13 (3): 259-264.
- Hoos I. Risk Assessment in Social Perspective. Perceptions of Risk. Washington: National Council on Radiation Protection and Measurement, 1980.
- 24. Hughes P, Ferrett E. Introduction to International Health and Safety at Work. London: Routledge, 2010.
- Mazur A. Does public perception of risk explain the social response to potential hazard. Q J Ideol 1987; 11 (2): 41–45.
- Kasperson R E, Renn O, Slovic P et al. The social amplification of risk: a conceptual framework. Risk Anal 1988; 8 (2): 177–187.
- Renn O, Burns W J, Kasperson J X, Kasperson R E, Slovic P. The social amplification of risk: theoretical foundations and empirical applications. J Soc Issues 1992; 48 (4): 137–160.
- Slovic P, Fischhoff B, Lichtenstein S. Why study risk perception. Risk Anal 1982; 2: 83–93.
- 29. Slovic P. The Perception of Risk. London: Routledge, 2016.

- Singh T D, Jayaraman T, Sharma B A. Assessment of radiological protection systems among diagnostic radiology facilities in North East India. J Radiol Prot 2016; 37 (1): 68.
- Stenzel P L. Acceptable risk?: Making decisions in a toxic environment by Lee Clarke. DePaul Law Rev 2014; 40 (4): 1165.
- Barke R P, Jenkins-Smith H C. Politics and scientific expertise: scientists, risk perception, and nuclear waste policy. Risk Anal 1993; 13 (4): 425–439.
- Johnson B B. Advancing understanding of knowledge's role in lay risk perception. Risk 1993; 4: 189.
- Tversky A, Kahneman D. Judgment under uncertainty: Heuristics and biases. Science. 1974; 185 (4157): 1124–1131.
- Finucane M L, Alhakami A, Slovic P, Johnson S M. The affect heuristic in judgments of risks and benefits. J Behav Decis Mak 2000; 13 (1): 1–17.
- Kumar R V, Bhasker S. Is the fast-paced technological advancement in radiation treatment equipment good for Indian scenario? J Cancer Policy 2015; 4: 26–30.
- Dikshit K R, Dikshit J K. North-east India: land, people and economy. Dordrecht, The Netherlands: Springer, 2014.
- Shimray U A. Socio-political unrest in the region called North-East India. Econ Polit Wkly 2004; 39 (42): 4637–4643.
- Atomic Energy Regulatory Board. Regulatory Inspection and Enforcement in Radiation Facilities, Manual NO. AERB/RF/SM/G-3. Mumbai: Atomic Energy Regulatory Board.

- International Atomic Energy Agency. Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 38. Vienna: International Atomic Energy Agency, 2006.
- International Atomic Energy Agency. Inspection of Radiation Sources and Regulatory Enforcement (Supplement to IAEA Safety Standards Series No. GS-G-1.5). Vienna: International Atomic Energy Agency (IAEA), 2007.
- Cha Y J. An analysis of nuclear risk perception: with focus on developing effective policy alternatives. Int Rev Public Admin 2004; 8 (2): 33-47.
- 43. World Health Organization (WHO). Quality Assurance in Radiotherapy. Geneva: WHO, 1988.
- Novotny J. Accidents in Radiotherapy: Lack of Quality Assurance?. Vienna: International Atomic Energy Agency (IAEA), 1997. http://www. iaea.org/inis/collection/NCLCollectionStore/\_Public/29/029/29029219.pdf. Accessed on 10<sup>th</sup> May 2017
- 45. Yeung T K, Bortolotto K, Cosby S, Hoar M, Lederer E. Quality assurance in radiotherapy: evaluation of errors and incidents recorded over a 10 year period. Radiother Oncol 2005; 74 (3): 283–291.
- 46. Diefenbach T. Hierarchy and Organisation: Toward a General Theory of Hierarchical Social Systems. New York, NY: Routledge, 2013.
- 47. Stoddart M C. Ideology, hegemony, discourse: a critical review of theories of knowledge and power. Social Thought Res 2007; 28: 191–225.