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Analysis of Factors Influencing Regulatory Compliance to Contain Man-made Ionizing Radiation from Medical Diagnostic Imaging Equipments in Corporate Hospitals, Tamil Nadu, India

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Authors' contributions

This work was carried out in collaboration between both authors. Author RR designed this study, conducted literature searches, designed the protocols, collected data, performed the statistical analysis and wrote the manuscript. Author RG has reviewed the manuscript for technical adequacy. Both authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Aims: To evaluate the current status of practices being followed to comply with regulatory guidelines by corporate hospitals for containing man-made ionizing radiation while using medical diagnostic imaging equipments. To statistically test and conclude whether Corporate Hospitals located in Metro and Non-metro cities, Revenue and Patient Queue Size influences the compliance.
Study Design: Descriptive Research design has been adopted in this study.
Place and Duration of Study: This study has been conducted in Tamil Nadu, India covering 25 metro and non-metro cities, for the period between June 2015 and May 2016.
Methodology: This research has scoped in 77 corporate hospitals who have expressed

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willingness to participate in this study out of 214 institutions approached. This study is based on the Regulatory guidelines published by Atomic Energy Regulatory Body, the Regulatory Body in India which controls the distribution and usage of Diagnostic Imaging equipments. This study has designed 7 dependent parameters (Regulatory, Layout Engineering, Technician Competency, Human Safety, Operations Know-How, Radiation Exposure Monitoring and Top Management Commitment). A structured questionnaire with 70 questions on a seven point scale (inclusive of zero) was constructed and administered for data collection. The parametric statistics has been adopted for statistical analysis of data.

Results: The mean of seven dependent variables have been found to be at the higher side of the measurement scale (Regulatory 5.64, Layout Engineering 5.62, Technician Competency 5.59, Human Safety 5.61, Operations Know-How 5.62, Radiation Exposure Monitoring 5.65 and Top Management Commitment 5.67). The corporate hospitals in Metro cities are found to exhibit significantly higher compliance when compared to non-metro, as confirmed by ANOVA results with 'F" ratio of 16.51, "P" value 0.00157 at a confidence interval of 99.5 percent and alpha value 0.005. Pearson's correlation coefficient 'rho' was found to be 0.057, with a "P" value (0.365) greater than alpha (0.05) at 99.5 percent confidence interval established weak and insignificant relationship between revenue and compliance index. Similarly, the patient queue size did not influence compliance index as revealed by correlation coefficient of 0.104, "P" value 0.312, alpha value 0.05 at 99.5 percent confidence interval.

Conclusion: It was quite evident from this research study that corporate hospitals have established very higher level of regulatory compliance with complete support and involvement of the Top Management. The top 5 key drivers that have led to such a superior level of regulatory compliance have been identified as Appoint full time Radiation Safety Officer, AERB Type approvals & renewals, Usage of TLD badge and testing dosage levels, Monitoring AERB approval policy and Engaging Service providers for equipment Servicing. This research study further recommends similar research work in other states of India and the requirement of a concrete mathematical model for estimation of Radiation Compliance Index.

Keywords: Corporate hospitals; atomic energy regulatory body; regulatory parameters; total quality management; radiation compliance index.

1. INTRODUCTION

1.1 Background of the Problem

The rising incidence of diseases, expanding middle class population and penetration of health insurance scheme and increasing awareness regarding preventive care is driving the India hospital market. The India hospital market is forecasted to cross US $ 189 billion by 2020. Interestingly, the Private sector in India dominates the country's hospital market [1]. Over the course of next five years, domestic as well as foreign private sector investments would be required in order to pump revenue growth in India hospital market and meet the demand for high quality healthcare services in the country. The "Emergence of advanced technologies such as telemedicine, cloud computing and growing popularity of day care surgery in India is projected to drive growth in India hospital market. [2]. Moreover, the accessibility to healthcare services for rural population can be improved with the use of cloud computing technologies, which not only increases accessibility of patient data across various geographies, but also reduces delays in diagnosis and treatment, by healthcare providers [3]. Hence, to meet this phenomenal demand and improve the Turnaround Time (TAT) of patient care, hospitals chose to attach diagnostic laboratories with complete facility for carrying out the initial diagnosis without causing any further delay. These diagnostic laboratories are equipped with Medical Diagnostic Imaging Equipments such as Computed Tomography (CT), Digital Radiography (DR), X-ray, Mammography and Bone Mineral Densitometer (BMD). The corporate hospitals intend to purchase refurbished and new diagnostic medical imaging equipments from inland and imports from other countries. However, commissioning of such equipments needs a formal clearance and approval from Atomic Energy Regulatory Body (AERB) in India. There were no restrictions on age of such used equipments until 2015. The regulatory change has been enforced by AERB which states that "the Pre-owned medical Diagnostic X-ray equipment which is more than seven years old shall not be imported in the

country"[4]. This has created the need for corporate hospitals to become transparent in their approach towards compliance on regulatory requirements such as hand-made ionizing radiation emitting equipments which have inherent risk of staff and technicians getting exposed to excessive radiation.

1.2 Research Question

Do Corporate Hospitals housing medical imaging equipments situated in metro and non-metro cities in India, have inherent risk of hand-made radiation exposure that follow the practices laid down by AERB on regular basis for radiation containment?

1.3 Literature Survey

Ever since radiation was discovered, people have benefited from its use in medicine and industry. Today, man-made sources of radiation globally account for about 21 percent of our total exposure. In industrialized countries it can be as high as 50 percent due to better access to medical imaging [5]. The radiation used in medical applications is the largest source of man-made radiation that people are exposed to. The majority of this exposure is from diagnostic X-rays, which are used by physicians to determine the extent of disease or physical injury [6]. In the field of nuclear medicine, radioactive compounds called radiopharmaceuticals are also used to support diagnoses, while a further source of radiation exposure is radiation therapy. The excessive exposure to radiation may lead to cancer related risks and there have been several researches in reducing the dosage levels used in patient scan [7].

The research studies have found that there has been a steep rise in use of imaging for diagnostic purposes. The usage of CT was increased by 14 percent, MRI by 26 percent and Ultrasound by 40 percent, over a ten year period. These studies have concluded that there is an urgent need to reduce the number of scans recommended by the physicians [8]. The research studies have found that more than 62 million CT scans are performed every year in United States, including at least 4 million for Children. Moreover, these studies have indicated that CT involves much higher doses of radiation as compared with plain-film radiography, resulting in a marked increase in radiation exposure in the population [9].

The staff working in the Intensive Care Unit is exposed to radiation continuously. A research study was conducted to estimate the annual cumulative radiation dose to individual ICU staff using thermo luminescent badges (TLD). A total of 44 staff including Radiologists have been asked to wear TLD badge for a period of 3 months. The estimated annual dosage to doctors and nurses on average was 0.99 mSv and 0.88 mSv respectively [10].

The article titled "How much Do CT Scans increase the Risk of Cancer?, published in Scientific American (1st July 2013 Shannon Freshwater), has discussed the growing need for diagnosis using CT scanner with less than 75 percent of the normal dose. This article has admitted that there are many people who receive unnecessary CT scan and along with them unneeded dose of radiation. It has mentioned that the emergency room physicians in particular order too many CT scans, making quick decisions in high-pressure situations that needs to be curtailed [11-13]. The need for corporate hospitals and institutions to develop and deploy a surveillance mechanism to identify patients with high cumulative radiation doses due to repeat imaging has been discussed in multiple research papers. These studies have shown plethora of instances of patients having gone through repeated CT scans leading to excessive radiation beyond 100 mSv, the threshold limits specified by the regulatory authorities [14].

The need for treating physician, assistants, and technologists involved in exposing pregnant women to radiation must know thoroughly the standard radiation safety practices. It has been suggested that regular interaction with companies providing the service contracts for the equipment and software packages should be done in keeping the departments updated regarding improvements and patient safety [15]. It has been projected more than 1 million women in Unites States have been over exposed to radiation while screening with Mammography within a span of three decades [16]. Modern research suggest that patients with Adolescent Idiopathic Scoliosis (AIS) undergo initial x-ray with standard digital radiography to eliminate differential diagnosis and micro-dose X-rays for follow-up purpose, to reduce the accumulation of ionizing radiation in long term [17].

There have been numerous recommendations on the usage of Exposure Index as a Quality Assurance tool to monitor correct use of equipment and observe variations in detector dose. The Results from such QA programmes

can be used to optimize exposures and provide radiographer continuing education and training in the use of Digital Radiography (DR) [18]. The review of literatures has emphasized the essential need for hospitals and diagnostic laboratories to understand how manufacturing industries have implemented Total Quality Management System and whether healthcare Industries have learnt the strategy for successfully implementing Regulatory standards for protecting from excessive radiation [19,20]. A research paper titled "Diagnostic Laboratories - Are these Radiation Safe?" has identified number of business process gaps that have led to poor implementation of Regulatory Systems [21]. A research work titled "Analysis of Regulatory Compliance On Radiation Safety Parameters with Chain of Diagnostic Centers in Tamil Nadu, India" has studied Regulatory compliance towards containing ionizing radiation [22]. So, this review has necessitated need for further research work to assess the effectiveness of regulatory system implementation in corporate hospitals to protect people from excessive radiation.

1.4 Scope

The Corporate Hospitals in Tamil Nadu, India registered with AERB for Diagnostic Scan services using imaging devices have been scoped for this research. The hospitals situated in Metro and Non-Metro cities accredited under National Accreditation for Testing and Calibration Laboratories (NABL) and Non-NABL has been included as a part of this research work.

1.5 Research Objectives

- To assess the current status of practices followed by the corporate hospitals in order to comply with the regulatory requirements stipulated by AERB
- To identify the Top 5 influencing factors that drives Regulatory compliance across the organizations
- To assess whether significant difference in compliance exists between corporate hospitals situated in Metro Cities and Non-Metro Cities
- To find out whether there is a significant relationship exists amongst Revenue, Patient Queue Size and Compliance Index.
- To find out the average age of medical diagnostic equipments commissioned and in-use

2. MATERIALS AND METHODS

2.1 Research Hypothesis

The following hypothesis has been developed by the researcher to test the association between location of hospitals in metro and non-metro on regulatory compliance.

H1: There will be no difference in regulatory compliance between corporate hospitals situated in Metro cities and Non-Metro cities

The impact of revenue on compliance towards controlling radiation has been conceptualized and narrated as a hypothesis.

H2: Revenue has a positive impact on the compliance

The hypothesis related to patient queue size and regulatory compliance has also been developed and cited.

H3: Patient Queue Size has a positive impact on the compliance

2.2 Research Design

2.2.1 Sampling procedure

The universe has been defined with a detailed search using "Google Search Engine", which has been conducted by the researcher through publicly available information sources. The search included List of Corporate Hospitals, AERB published X-Ray users and NABH accreditation board data base respectively. The Universe included corporate hospitals having any one of Imaging Radiological Equipments (CT, X - Ray, BMD and Mammography). The researcher reviewed them on the basis of their license and approval by AERB through publically available information source. The licensed and approved corporate hospitals with medical diagnostic equipments attached within their facilities Tamil Nadu is 214, which stands as a definite universe of this research study. Finally, 77 respondents who have agreed to participate in the research study were included as samples. The stratified random sampling technique has been adopted to identify the samples randomly from each stratum.

2.2.2 Data collection techniques

This study was targeted to collect and collate primary data from corporate hospitals attached

with diagnostic centers using Diagnostic Imaging Equipments. The data collection has been carried out on institutions adhering to best practices and complying with the requirements and standards of AERB regulatory and operational guidelines. The Radiologists and Technicians involved in managing the equipment have been identified as target touch points for collecting the data. The professionals having thorough knowledge on modus operandi of X-Ray equipments, day-to-day usage, limitations and precautionary measures was quite appropriate to be as samples for the present study so as to provide the data on existing practices required for this study. An email has been sent to all 214 listed corporate hospitals top management explaining the research study objectives and seeking access and approval to contact their technicians and Radiologists. The need for this study and the impending benefits has been explained by the researcher. The researcher has received consensus from 77 corporate hospitals for carrying out the data collection. A confidentiality agreement has been signed with all the participating hospitals. The researcher has sent a detailed communication about this study to Technicians and Radiologists on this study objective and explained the method of answering the questionnaire.

2.2.3 Data collection instruments

The literature review on various research studies exhibited the non-existence of a standard prior instrument for measuring the best practices based on AERB guidelines for Medical Diagnostic Imaging in India. Hence, the researcher developed an instrument as per the requirements of study with seven different parameters such as Regulatory, Layout Engineering, Technical Competency, Human Safety, Operations Know-How, Monitoring Radiation Exposure and Management Commitment. The list of verification points under each parameter have been devised for assessing the practices and continuous adoption of standards. A seven-point scale has been used in the questionnaire against every item and choice of seven-point scale has been quite consistent with the existing literature on TQM and ISO systems [23] (Table 1).

2.2.4 Reliability of the instrument

The reliability of the instrument has been tested in accordance with the recommended best practices to verify whether it yields the same results on repeated trials [24]. The most popular reliability estimate has been given by Cronbach's Alpha [25]. The value of alpha varies between "0" and "1". As a general rule, reliability should not be less than 0.80 and supported by the fact that at that (0.80) level correlations are attenuated very little by random measurement error. The reliability test has been conducted with SPSS (version 20.0) for examining the consistency of the measurement instrument used in this research. The test result has indicated "no exclusions" (Refer Table 2) and Cronbach's alpha value as 0.967 (Refer Table 3). The Cronbach's alpha value estimated for the measurement scale used in this research is 0.967, which is well above the accepted limit of a minimum 0.80. Hence, scales used in the measurement tool have been construed as reliable.

Table 1. Measurement scale and description

0	1	2	3	4	5	6
No Practice Exist	Marginal Presence	Moderate Presence	Significant Presence	High Presence	Very High Presence	Complete Presence

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Table 2. Scale reliability test summary

Scale reliability test summary			
	Summary	**Total size (N)**	**Percentage**
Cases	Valid	70	100
	Excluded	0	0
	Total	70	100

Table 3. Cronbach's Alpha Test Results

Cronbach's alpha estimation	
Cronbach's alpha	**Number of items**
0.9673	70

3. RESULTS AND DISCUSSION

3.1 Regulatory

The data collected from corporate hospitals has been collated and number of responses for each variable under this study was first grouped for a detailed analysis. The responses on compliance to meet all nine specified regulatory requirements stipulated by AERB, based on the routine day to day practices (Table 4) and the corresponding mean have been drawn-up and tabulated (Table 4). It has been evident from the data shown in Table 4, the compliance was found to be between 'high (4) and completely present (6)", which is on the higher end of 7 point measuring scale. More than 70 percent of the respondents have answered that day-to-day practice followed by these institutions to comply with regulatory requirements are always completely present.

The graphical distribution of percentage of responses (Fig. 1) across the spectrum of measuring scale has identified the key focus areas for implementation with regard to Regulatory parameter, wherein more than 70 percent of respondents favored complete presence of practices. The following factors have been found to have greater influence in prioritizing the implementation of regulatory compliance, which is based on the cumulative percent of responses on practices that exceeds high compliance:

- Continuous monitoring of AERB approval policy (100 percent)
- On-time renewal of expired AERB approvals (100 percent)
- Ensuring the facility housing medical imaging equipment approved by AERB (92 percent)
- Procurement of only AERB type approved equipments (92 percent)

3.2 Layout Engineering

The responses on compliance to layout engineering under various measurement scales has been grouped and shown in Table 5, for all seven requirements to safely commission the diagnostic equipments with adequate protective measures for containing excessive radiation. As AERB layout engineering guidelines specify the minimum room dimensions required, the type of material to be used for construction and other measures for minimizing excessive radiation compliance to this parameter signifies greater importance. The distribution of responses from Table 5 has shown that the compliance to layout engineering was found to be between High (4) and Very High (6) levels.

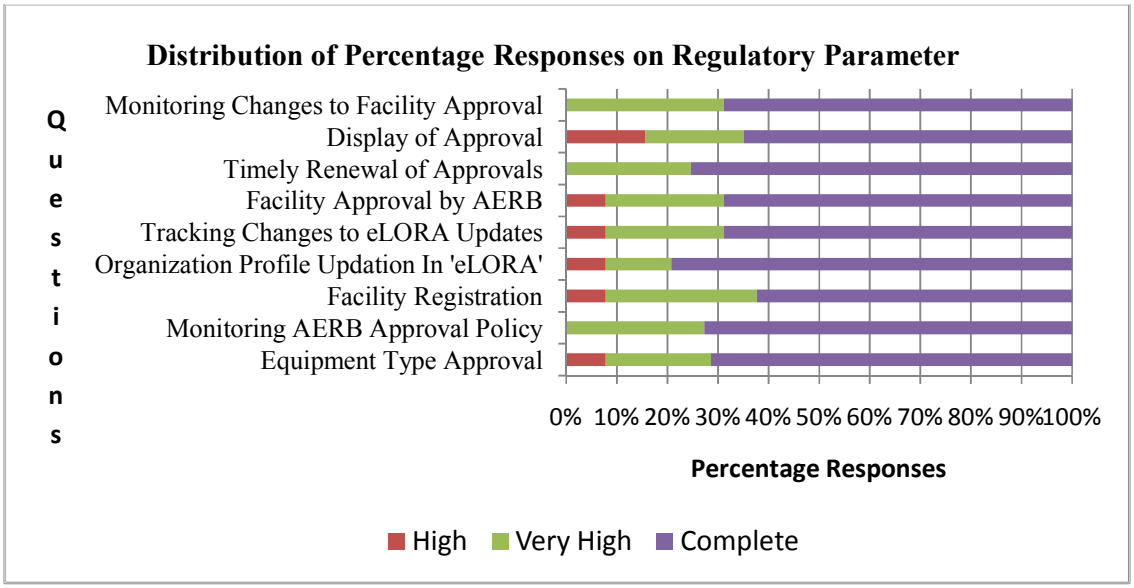

Fig. 1. Distribution of percentage of responses on regulatory

Table 4. Distribution of responses on regulatory compliance

Sl. No	Questions	Number of responses			Mean
		High (4)	Very high (5)	Completely present (6)	
1	Equipment Type Approval	6	16	55	5.65
2	Monitoring AERB Approval Policy		21	56	5.73
3	Facility Registration	6	23	48	5.55
4	Organization Profile Updation in 'eLORA'	6	10	61	5.71
5	Tracking Changes to eLORA Updates	6	18	53	5.61
6	Facility Approval by AERB	6	18	53	5.61
7	Timely Renewal of Approvals		19	58	5.75
8	Display of Approval	12	15	50	5.49
9	Monitoring Changes to Facility Approval		24	53	5.69
		Overall Mean			5.64

Table 5. Distribution of responses on layout engineering

Sl. No	Questions	Number of responses			Mean
		High (4)	Very High (5)	Completely present (6)	
1	Equipment Layout Approval		30	47	5.61
2	Tracking Changes to Layout Approval		27	50	5.65
3	Commissioning Lead Door	9	18	50	5.53
4	Monitoring the Usage of Lead Door	6	16	55	5.64
5	Use of AERB Approved Material for Construction	6	20	51	5.58
6	Repair Work Material Usage Policy	6	12	59	5.69
7	Instituting Independent Technician Room	6	15	56	5.65
		Overall Mean			5.62

The graphical distribution of percentage of responses for layout engineering (Fig. 2) revealed that corporate hospitals do not compromise compliance on equipment layout engineering controls. However, based on the cumulative compliance percentage, the following specific requirements gained larger momentum while implementation of controls pertaining to layout engineering.

- Obtaining Equipment Layout Approval in the Blue Print from AERB (100%)
- Tracking Changes to Layout Approval (100%)

All other requirements have scored more than 90 percent compliance above high level and they are the subset of Equipment Layout engineering requirements.

3.3 Technician's Competency

The responses on Technician's competency has been grouped and shown in Table 6. It was evident from the data that compliance to appointing skilled technicians for effectively managing the diagnostic equipment and continuous upgradation of skills has been assessed between High (4) and Completely Present (6). From the percentage distribution of compliance as shown in Fig 3, 63 percent respondents have agreed that the practice of appointing highly skilled technicians is fully present, while another 20 percent of respondents have expressed their acceptance on High Compliant area. The competency enhancement seems to have been well handled through continuous skill upgradation program (100 percentage cumulative responses favoring above very high level of compliance, Fig 3) and training on software application functionalities by the equipment manufacturer (80 percent responses favored above very high compliance, Fig 3).

The graphical distribution of percentage of responses (Fig 3) has brought out two focus areas for implementation as indicated below:

- Training by equipment manufacturer's application specialist to impart knowledge on nuances of handling the software functionalities

- Management commitment in organizing additional training program for skill upgradation

3.4 Human Safety

The exposure to radiation by technician's while performing the scan can be accurately measured based on the compliance to wearing Thermo Luminescent Dosimeter (TLD) badge and protecting it in safe place when not in use. The intensity of light emitted is dependent upon the radiation exposure. Moreover, the periodical certification of proper functioning of the equipment by deploying competent third party to perform Quality Assurance Test plays a critical role in protecting people working with and around the equipment from excessive radiation. The responses on measures and compliance to protect the safety of Technicians and Radiologists has been grouped and shown in Table 7. The compliance to Human Safety related parameters has been found to be between High (4) and Completely Present (6) levels.

The graphical representation of percentage distribution on Human Safety related parameters has been shown in Fig 4. This plot has highlighted that 'equipment Quality Assurance test' and 'compliance to wearing TLD badge' are the key focus areas with more than 90 percent respondents and they have agreed on compliance to be based on day-to-day practices for meeting these requirements are high and completely present.

3.5 Operations Know-how

A collimator is a device that narrows a beam of particles or waves. The narrowing of beam refers to either to cause the directions of motion to become more aligned in a specific direction, or to cause the spatial cross section of the beam to become smaller. Here, the technician must be very thorough on the technological aspects of medical devices and manipulate the collimator effectively for controlled exposure to radiation. The technician's working knowledge of the equipment under varying temperature and humidity conditions is vital for not only protecting the device from unplanned malfunction but also help preserving key components of the equipment for specified shelf-life. The responses towards compliance on Operations Know-How has been compiled and represented in Table 8. The spread of responses is found to be between High Compliant (4) and Completely Compliant (6).

The graphical representation of percentage responses on Operations Know-How shown in Fig.5 indicates that compliance towards ensuring the right temperature and humidity inside the equipment room, usage of pediatric protocols, protecting abdomen while scanning pregnant woman, signage's and radiation stickers to direct patients and staff and safe storage of TLD Badge when not in use, which is found to be always above Very High Level (5) and Completely Present (6). The cumulative percentage responses on compliance to above parameters are estimated to be 100. However, compliance to skillful handling of collimator exhibited 88 percent of cumulative rating for High and Very high levels.

3.6 Monitoring Radiation Exposure

The compliance on best practices implemented towards monitoring radiation exposure has been compiled and presented in Table 9. The Quarterly submission of TLD Badges with AERB approved third party laboratories for detailed analysis of dosage levels of technician has been found to be very highly complaint. The system of managing incidents with regard to actual dosage level has been reported to be higher than the threshold limit by promptly releasing technician on a paid leave until the normalcy occurrence has been rated to be between High (4) and Completely Present (6).

Table 6. Distribution of responses on technician's competency

Sl. No	Questions	Number of responses			Mean
		High (4)	Very High (5)	Completely present (6)	
1	Highly Skilled Technician	6	23	48	5.61
2	Program for Continuous Skill Upgradation		27	50	5.65
3	Radiation Exposure Parameters Display	10	14	53	5.53
4	Track Updates to Parameters		24	53	5.64
5	Training by Application Specialist	16	3	58	5.58
		Overall Mean			5.59

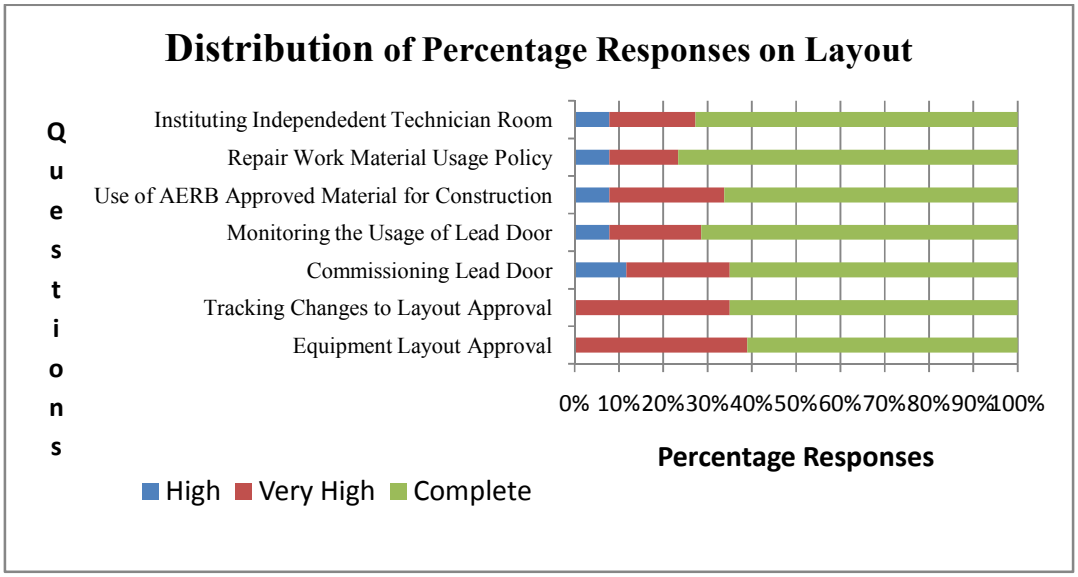

Fig. 2. Distribution of Percentage of Responses on Layout

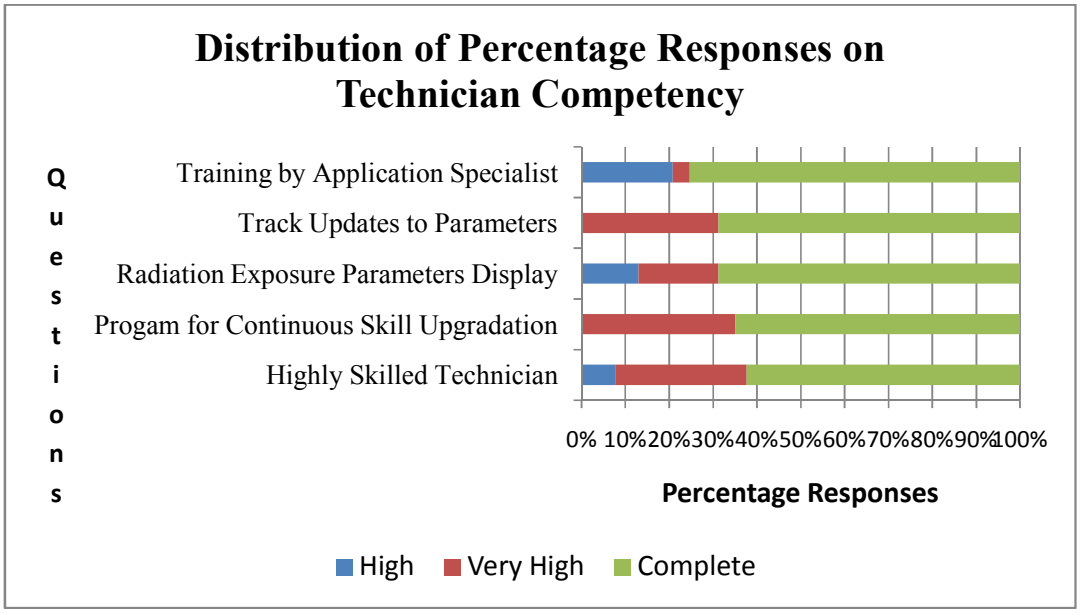

Fig. 3. Distribution of percentage of responses on technician's competency

Table 7. Distribution of responses on human safety

Sl. No	Questions	Number of responses			Mean
		High (4)	Very high (5)	Completely present (6)	
1	Wearing TLD Badge During Scan	6	18	53	5.61
2	X-ray Room Door Closure Monitoring	16	3	58	5.55
3	Avoid Crowding at X-ray Room	9	5	63	5.70
4	Usage of Lead Aprons for Mobile X-ray	9	18	50	5.53
5	Equipment Quality Assurance Test at Installation		24	53	5.69
		Overall Mean			5.61

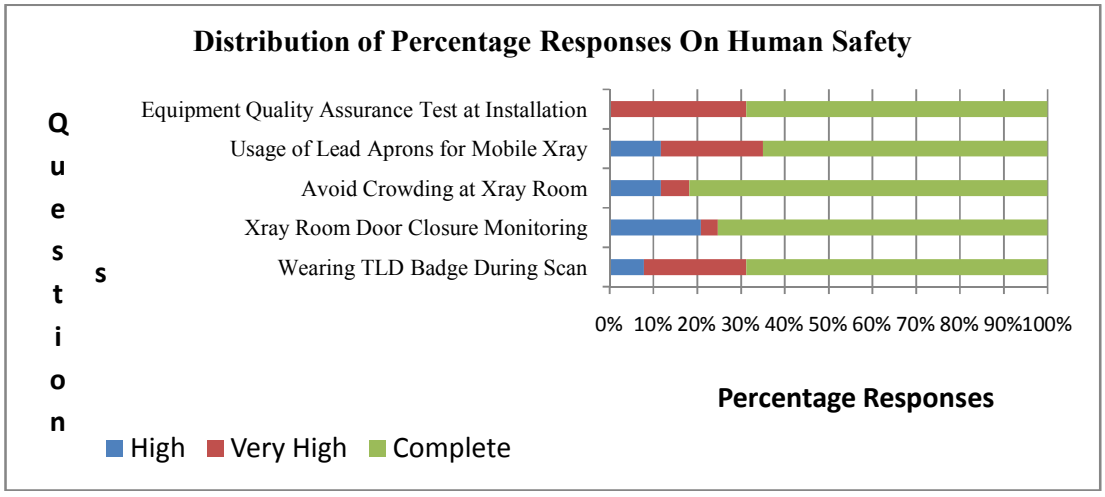

Fig. 4. Distribution of percentage of responses on human safety

Table 8. Distribution of responses on operations know-how

Sl. no	Questions	Number of responses			Mean
		High (4)	Very high (5)	Completely present (6)	
1	Collimator Usage	10	14	53	5.56
2	Protecting Abdomen while Scanning Pregnant Woman		29	48	5.62
3	Storage of TLD Badge when not in Use		27	50	5.65
4	Signage's and Radiation Stickers		24	53	5.69
5	Usage of Pediatric Protocols		30	47	5.61
6	Maintenance of Environmental Conditions		27	50	5.65
		Overall Mean			5.62

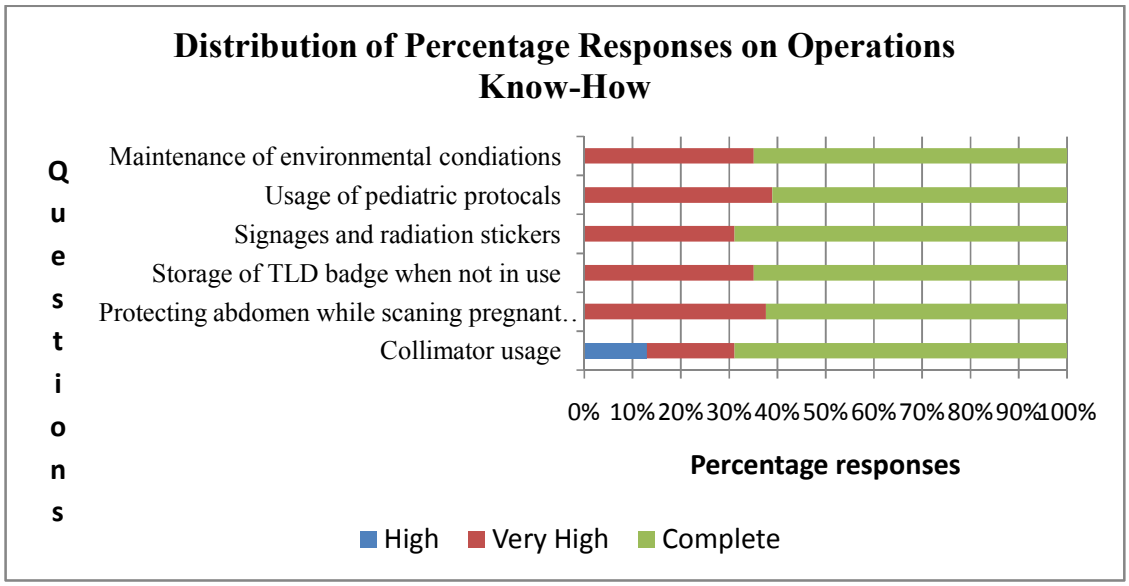

Fig. 5. Distribution of percentage of responses on operations know-how

Table 9. Distribution of responses on monitoring radiation exposure

Sl. no	Questions	Number of responses			Mean
		High (4)	Very high (5)	Completely present (6)	
1	Timely Submission of TLD Badge for Analysis (Quarterly)		19	58	5.75
2	Monitoring the Dosage Levels of Technician	9	5	63	5.70
3	Performing Periodical QA test (Every 2 Years)	9	18	50	5.53
4	Managing Exposure Incidents		24	53	5.69
5	Evaluating AERB Approved Service Providers	10	14	53	5.56
		Overall Mean			5.65

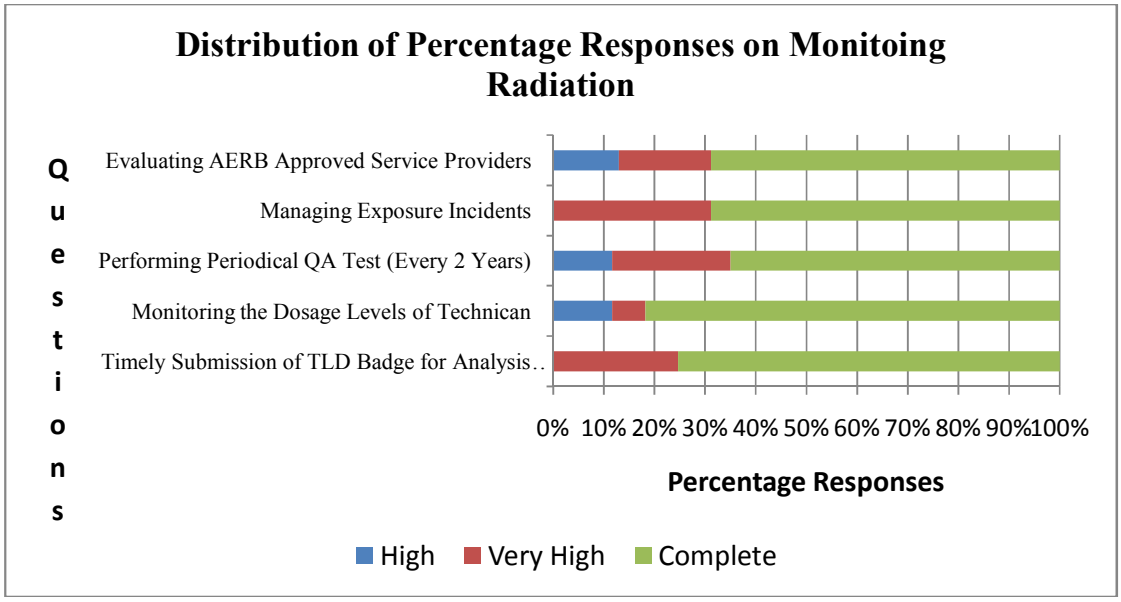

Fig. 6. Distribution of Percentage of Responses on Monitoring Radiation

The percentage responses on compliance with respect to Monitoring Radiation Exposure (Shown in Fig 6) has categorically established that timely submission of TLD Badges (with more than 70 percent of respondents favored complete presence of the practice) and continuous monitoring of technician's exposure levels (with more than 80 percent of respondents agreed on complete presence of the practice) are the key focus areas for implementation of fool-proof monitoring system.

3.7 Top Management Commitment

The success of any change program is largely decided by the extent of Top Management involvement and commitment shown throughout the change management cycle. Hence, the regulatory system implementation must be considered as a larger change program and the Top Management should devise clear strategies in propagating this change until successful implementation. The responses to Top Management commitment on various parameters benchmarked for this study has been compiled and shown in Table 10. It has been observed that the Top Management commitment was strongly exhibited with regard to compliance spectrum ranging between Very High level (5) and Completely Present (6). It could be inferred from Table 10 that 68 out of 77 corporate hospitals have agreed on uncompromising commitment in establishing compliance to engage third party service providers for equipment maintenance and has been in to existence with complete presence of such system. The appointment of full-time Radiation Safety Officer (RSO), who spear heads this change has been reported to be completely presence in 58 corporate hospitals and very high

presence in 19 corporate hospitals. The Top Management involvement in appointing qualified suppliers for conducting Quality Assurance (QA) test, understanding the outcome of QA test, allocating sufficient funds for resources and materials and organizing expert training for technician were found to be very high. The distribution of percentage responses as shown in Fig 7 has supported this observation. This concludes that corporate hospitals have the complete buy-in of Top Management and that seems to be a key factor that accounts for a high level of regulatory compliance.

3.8 Hypothesis Testing

In order to test the existence of significant differences with regard to regulatory compliance between corporate hospitals located in Metro and Non-metro cities, ANOVA has been adopted by the researchers. The hypothesis to understand this relationship titled "*No Significant difference exists between Metro and Non-metro zone corporate hospitals on compliance to contain radiation*" has been framed. The mean compliance score between metro and non-metro hospitals has been compiled and tabulated (Table 11).

The ANOVA test has been performed at 99.5 percent confidence level with alpha value "0.05". The test results have shown 'F" value as 16.51, degrees of freedom at 13, and "**P**" value 0.00152 (Table: 12). The estimated "P" value (.001572) is found to be less than alpha value (0.05),. Hence, the null hypothesis is rejected. This result does not support the argument assumed by researchers that there will be no significant differences between metro and non- metro corporate hospitals. Hence it is concluded from the analysis that average compliance score of corporate hospitals in metro cities significantly differs from non-metro corporate hospitals.

3.9 Relationship between Revenue and Compliance Score

The relationship between Revenue and Compliance score has been tested by estimating Carl-Pearson Correlation Co-efficient. This test was conducted with an Alpha value of 0.05 at 99.5 percent confidence interval and Pearson co-efficient (Rho) was found to be + .057. This indicates the existence of a very weak positive correlation between Revenue and Compliance Score, which is insignificant as inferred from 'P' value of 0.368, higher than the alpha value. Hence, the null hypothesis 'Revenue has a Positive impact on Compliance Score' has been rejected. This elucidates that Corporate Hospitals consider regulatory compliance as a fundamental pillar for protecting technicians and staff from excessive hand-made ionizing radiation emitted by Diagnostic Medical Imaging Equipments without linking the investment to revenue earned. The Fig. 8 shows correlation between revenue and regulatory compliance.

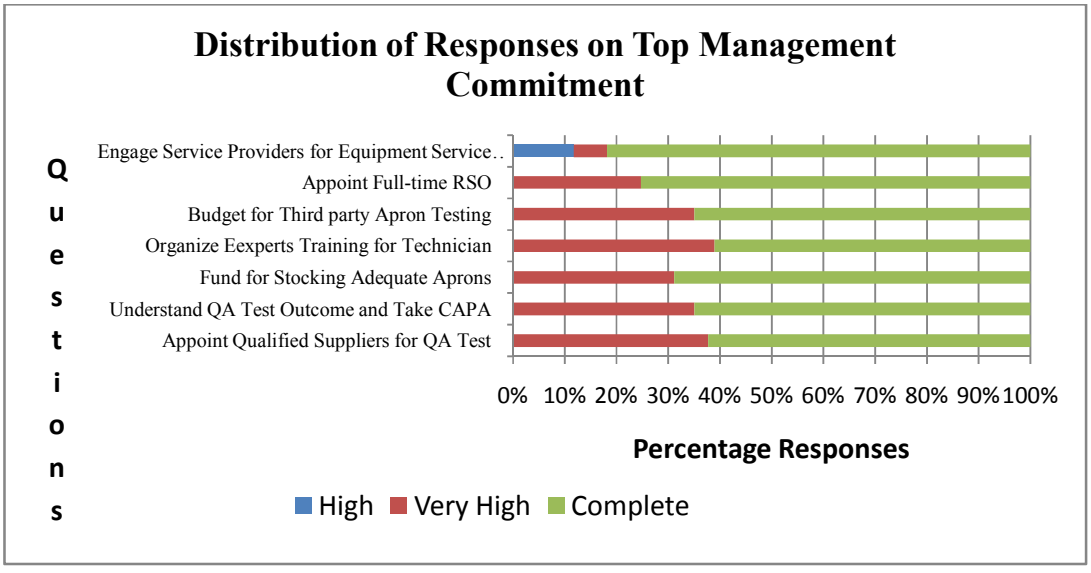

Fig. 7. Distribution of percentage of responses on top management commitment

Table 10. Distribution of responses on top management commitment

Sl. No	Questions	Number of responses			Mean
		High (4)	Very high (5)	Completely present (6)	
1	Appoint Qualified Suppliers for QA Test		29	48	5.62
2	Understand QA Test Outcome and take CAPA		27	50	5.65
3	Fund for Stocking Adequate Aprons		24	53	5.69
4	Organize Experts Training for Technician		30	47	5.61
5	Budget for Third Party Apron Testing		27	50	5.65
6	Appoint Full-time RSO		19	58	5.75
7	Engage Service Providers for Equipment Service Contracts	9	5	63	5.70
		Overall Mean			5.67

Table 11. Mean compliance score between metro and non-metro zones

Sl. no	Compliance parameter	Metro	Non-Metro
1	Regulatory	5.67	5.38
2	Layout	5.65	5.35
3	Competency	5.61	5.48
4	Safety	5.64	5.40
5	Know How	5.63	5.63
6	Exposure Monitoring	5.66	5.55
7	Commitment	5.68	5.57

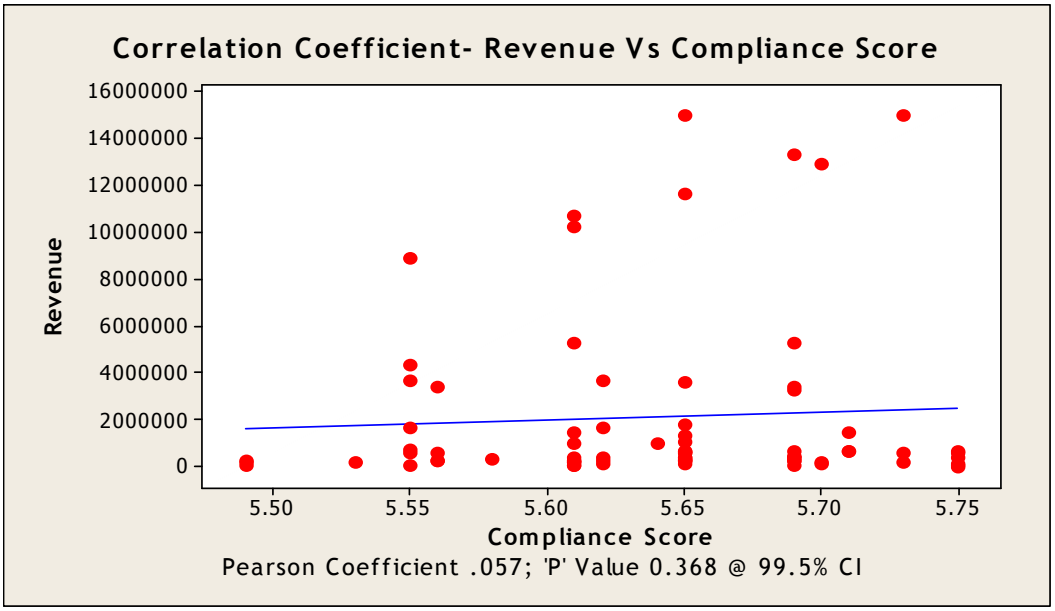

Fig. 8. Correlation between revenue and regulatory compliance

3.10 Relationship between Patient Queue Size and Compliance Score

The relationship between Patient Queue Size and Compliance score has been tested using Carl-Pearson Correlation Co-efficient with Alpha value of 0.05 at 99.5 percent confidence interval. The Pearson co-efficient (Rho) was found to be +.104. This indicates a very weak positive correlation between Revenue and Compliance Score which is insignificant as inferred from '**P**' value of 0.312, higher than the alpha value. Hence, the Null Hypothesis (Patient Queue Size has a Positive impact on Compliance Score) has been rejected. This is a test on Top Management Commitment as in majority of the business

unique practices on Regulatory compliance are used as Marketing Advantage to pull more patients. However, it was evident from the correlation study (Fig 9) that Top Management put compliance above revenue and strategy to invite more patients.

Table 12. ANOVA results

Source	SS	df	MS	
Between	0.1	1	0.1	'F' Value
Within	0.072	12	0.006	16.51067
Total	0.172	13		

The 'F'-ratio value is 16.51067. The 'P'-value is .001572. The result is significant at 'P' < .05.

3.11 Life of Existing Imaging Equipments

The age of existing diagnostic imaging equipments has been computed taking installation year (data collected from the questionnaire) as the start date and this research study conducted year (June 2017) as the end date. This ageing was estimated for Computed Tomography (CT) and Digital Radiography (DR) considering their extensive day-to-day usage pattern. The descriptive statistics has shown the following results (Table 13).

The average age of medical diagnostic equipments is found to be 9.47 years for CT and 9.01 years for DR. The maximum age of DR and CT has been estimated to be 16 years and minimum age was 3 completed years. The run chart of these equipments age is shown in Fig. 10.

This research study has identified that all corporate hospitals included in this study have procured new CT and DR equipments. This clearly underlines corporate hospitals procurement policy favors purchase of new equipments' over refurbished machines. The average age of these key equipments (CT and DR) has crossed the threshold limit of 7 years set by AERB for procuring refurbished equipment. This inference draws significance points and leads to further discussion by the policy makers to set similar norms for the life span of new equipments and controls to be exercised for minimizing the exposure to radiation.

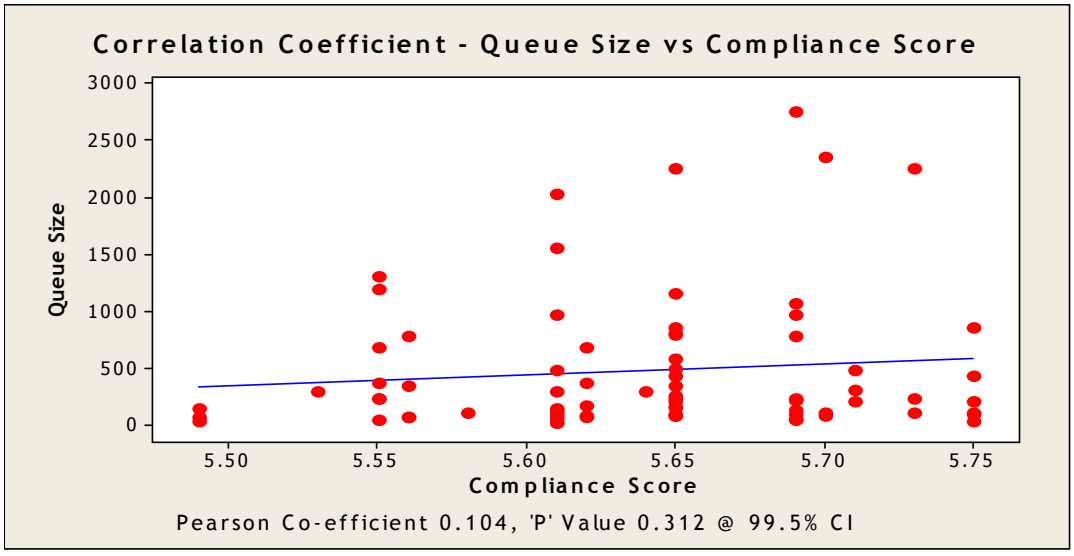

Fig. 9. Correlation between patient queue size and regulatory compliance

Table 13. Descriptive statistics on age of medical devices

Measurement parameter	CT (Elapsed Years)	DR (Elapsed Years)
Average	9.47	9.01
Minimum	3	3
Maximum	16	16
Median	10	10
Standard Deviation	3.5	3.2

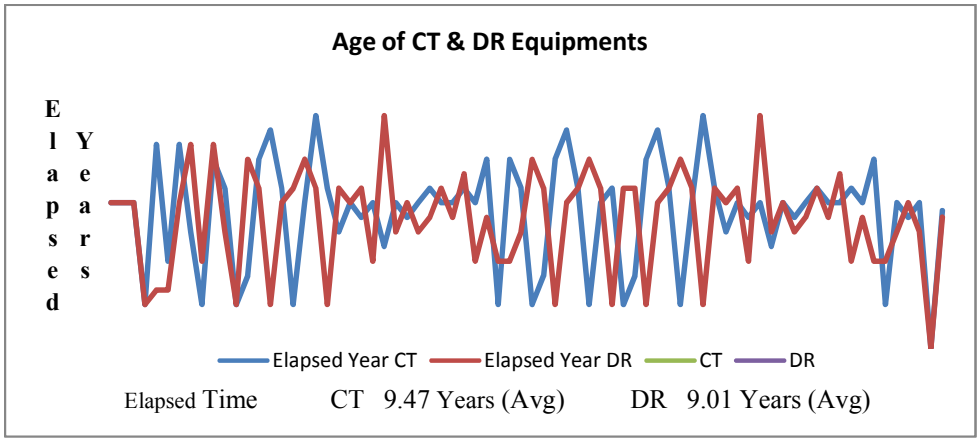

Fig. 10. Run chart of medical diagnostic equipments age

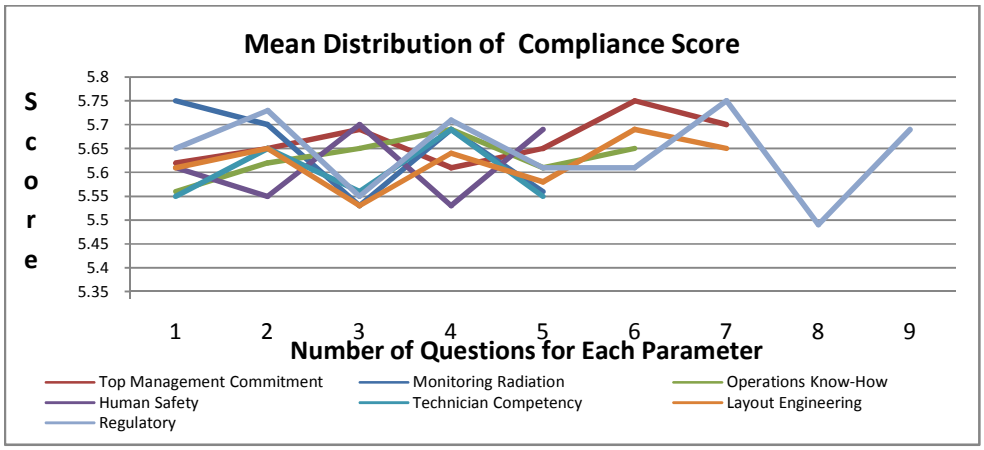

Fig. 11. Run chart of mean compliance score

Table 14. Top 5 regulatory compliance drivers

Sl. no	Compliance variable	Key compliance driver	Cumulative *Responses	Mean (On a scale of 6)	Rank
1	Top Management Commitment	Appoint Full- time Radiation Safety Officer	77	5.756	**1**
2	Regulatory	AERB Type Approvals & Renewals	77	5.754	**2**
3	Monitoring Radiation Exposure	Usage of TLD Badge and Testing Dosage Levels	77	5.753	**3**
4	Regulatory	Monitoring AERB Approval Policy	77	5.730	**4**
5	Top Management Commitment	Engaging Service Providers for Equipment Servicing	68	5.700	**5**

*Note: *Cumulative response has been computed by adding Very High Compliant and Completely Present Practices*

3.12 Comparison of Mean Score among the Dependent Variables

The mean score estimated for all the seven dependent variables analyzed in this research study has shown the following values: *Regulatory 5.64, Layout Engineering 5.62, Technician competency 5.59, Human Safety 5.61, Operations Know-How 5.62, Monitoring Radiation Exposure 5.65 and Top Management*

commitment 5.67). The run chart of mean compliance scores (Fig 11) supports this argument.

3.13 Top 5 Regulatory Compliance Drivers

The Top 5 Regulatory compliance drivers which influenced corporate hospitals (Table 14) in setting-up of highly complaint business practices have been identified in this present research and are based on the cumulative number of responses on higher end of Compliance Spectrum and Mean Compliance Score. Also, they have been found to be instrumental in translating and disseminating Regulatory Compliance Standards across various levels in the hospital.

4. CONCLUSION

Based on the detailed analysis and statistical inferences of this research study, it has been concluded that corporate hospitals exhibit very high level of commitment for establishing innovative systems and business practices towards implementation of Regulatory Compliance. Furthermore, all the seven dependent variables taken in this research study have shown superior compliance on the higher side of measurement scale between 5.59 and 5.62 on a 6 point scale. This illustrates that there has been significant importance and priority assigned to all the functions of corporate hospitals towards radiation control measures implementation.

The corporate hospitals situated in metro cities have excelled on better compliance to safeguard their staff and patients from exposure to excessive ionizing radiation than non-metro hospitals. The revenue did not have any significant effect on radiation compliance. This in turn promotes the Top Management commitment towards building compliance-centric business model in which the social well-being has to be given top most importance than meeting financial oriented business objectives. The patient queue size also did not significantly impact radiation compliance which reveals that the intent of business users is not to conceive regulatory compliance investment and best practices as marketing advantage.

It was evident from the study that Top Management has played a key role in establishing a successful model for driving regulatory compliance, by appointing a qualified Radiation Safety Officer (RSO), who is the champion for spear-heading this change and eventually ranked as “1” with a mean score of 5.756 on a 6 point scale. In furtherance, this research study further recommends similar research work to be extended in Government Hospitals within Tamil Nadu, India to understand the compliance management system in practice and compare with corporate hospitals. This study has identified the adequate scope for future research by designing a mathematical model for scientific estimation of Radiation Compliance Index.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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