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A Comprehensive Analysis of Best Practices towards Radiation Safety Measures for Medical Diagnostic Imaging Equipments in Government Hospitals, Tamil Nadu, India

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Author's contribution

The sole author conceptualized the need for this study, conducted literature searches, designed the protocols, collected data, performed the statistical analysis and prepared the manuscript.

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ABSTRACT

Aims: To evaluate the current maturity of business processes evolved and implemented to comply with regulatory guidelines by Government hospitals for containing man-made ionising radiation while using medical diagnostic imaging equipments. To statistically test and conclude whether any significant differences exist in day-to-day practices between Metro and Non-metro cities hospitals. To test and conclude whether patient queue size influences regulatory compliance score.
Study Design: Descriptive Research design has been adopted in this study.
Place and Duration of Study: This study was conducted in Tamil Nadu, India covering 33 metro and non-metro cities, for the period between July 2016 and March 2017.
Methodology: This research has sampled 38 Government hospitals spread across Tamil Nadu, India who has agreed to participate and provide information in this study out of 42 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, 7 dependent parameters (Regulatory, Layout Engineering,

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Technician Competency, Human Safety, Operations Know-How, Radiation Exposure Monitoring and Top Management Commitment) and a structured questionnaire with 70 questions on a seven point scale (inclusive of zero) was constructed and administered for data collection. Non-parametric statistics has been adopted for statistical analysis of data.

Results: The analysis of compliance data has shown exceptional compliance in all the variables studied and found to be at the higher side of the measurement scale (Regulatory 5, Layout Engineering 6, Technician Competency 6, Human Safety 6, Operations Know-How 6, Radiation Exposure Monitoring 6 and Top Management Commitment 6). The Chi-square test has concluded that there is no significant difference in regulatory compliance score between Government hospitals in metro cities and non-metro cities (Minimal chi-square value 0.109547; df 6 and *'P*' value 0.9999). Spearman Rank correlation coefficient 'rho' was found to be - 0.095, with a "P" value (0.5712) more significant than alpha (0.05) at 95 percent confidence interval established very weak negative and insignificant relationship between patient queue size and compliance index.

Conclusion: It was quite evident from this research study that Government hospitals have established an extraordinary level of regulatory compliance (between Very High Compliance and Complete Presence of best practices recommended by AERB).The most distinguishing feature that has led to superior compliance is the full-time availability of Radiation Safety Officer as a change leader in all the hospitals. The patient crowd size did not influence compliance score, and it was due to the inherent nature of superior commitment from Top Management. This research study further recommends similar research work in other states of India and high tech global practices in information security prevalent in monitoring hospitals for safeguarding Patient Health Information (PHI).

Keywords: Government hospitals; atomic energy regulatory body; radiation safety officer; total quality management; radiation compliance index.

1. INTRODUCTION

1.1 Background of the Problem

Today, nearly half of the exposure of the U.S. population to radiation comes from medical sources according to the National Council on Radiation Protection and Measurements (NCRP). It was cited in research work on 'Radiation Risks From Medical Imaging' that most medical exposure comes from the use of standard x-rays and CT scans to diagnose injuries and diseases in patients [1]. The radiation dose absorbed by a person is measured using the standard unit rad or gray (Gy). The biological risk of exposure to radiation is estimated using the conventional unit millisievert (mSv). The United Nations Scientific Committee on the Effects of Atomic Radiation has published in their website for public access about the data on radiation dose range and effect of human health, which has been extracted and described in Table 1.

The U.S Food and Drug Administration (FDA) in their website under radiation-emitting products section has explained the radiation risks from CT. They have also estimated that the effective doses from diagnostic CT procedures are typically in the range of 1 to 10 mSv. The risk of developing cancer as a result of exposure to radiation depends on the part of the body exposed, the individual's age at exposure, number of times the procedure is repeated, the individual's gender and the longevity of exposure. The Harvard Health Publication, under 'Women's Health Watch Section' has described that the proportion of total radiation exposure that comes from medical sources has grown from 15 percent in the early 1980s to 50 percent today [2]. The CT alone accounts for 24 percent of all radiation exposure in the United States, according to a report issued in March 2009 by the National Council on Radiation Protection and Measurements [3].

The usage of medical imaging devices at diagnostic centers and hospitals, which emanates man-made ionising radiation, is regulated through country-specific Regulatory body. In India, Atomic Energy Regulatory Body (AERB) monitors and ensures implementation of Government policies and radiation safety standards while procuring, commissioning and maintaining these equipments. India as a country encourages the use of refurbished (used) and new medical imaging devices, estimation of risk of exposure to excessive radiation in the context of increased use of CT and X-ray devices plays paramount importance [4]. The Report on 'India Diagnostic Imaging Equipment Market- Growth,

Table 1. Radiation dose levels vs effect on human health

Sl. no	Dose range	Effect of human health
1	Up to 10 mSv	No direct evidence of human health effects
2	10 - 1000 mSv	No early effects; increased incidence of certain cancers in exposed populations at higher doses
3	1000 - 10 000 mSv	Radiation sickness (risk of death); increased incidence of certain cancers in exposed populations
4	Above 10 000 mSv	Fatal always

Trends and Forecasts (2016- 2021)' published by Mordor Intelligence in November 2016 has projected that India is poised for phenomenal growth in healthcare with a focus on Diagnostic center expansion in Tier II and Tier III cities [5]. Hence, there would be humungous demand for AERB regulatory approvals and the need to establish compliance with the regulatory requirements for protection of the public from the excessive radiation by these new hospitals and diagnostic centers to come.

1.2 Research Question

The Government being a policy maker and controlling the distribution and effective usage of Diagnostic Medical imaging equipments through Atomic Energy Regulatory Body across India, Do Government Hospitals exhibit a high level of regulatory compliance to contain excessive man-made ionizing radiation for protecting people?

1.3 Literature Survey

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (The BSS,) specify requirements for the protection of health against exposure to ionizing radiation and for the safety of radiation sources [6]. The BSS, which are based upon information on the detrimental effects attributed to radiation exposure provided by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [7]. The recommendations of International Commission on Radiological Protection (ICRP, 1991), is intended to provide the basis for the regulation of both 'practices' and 'interventions [8]. In India, AERB has published standards for 'Radiation Safety in manufacture, Supply and Use of Medical Diagnostic X-ray Equipment' which specifies the Design requirements for an X-ray equipment, Regulatory requirements for Manufacturers of X-ray equipment, Regulatory requirements for the use of X-ray requirements and responsibilities of various stakeholders including Radiation Safety Officer [9].

CT imaging involves the use of x-rays, which are a form of ionizing radiation. The exposure to ionizing radiation is known to increase the risk of cancer. The guidelines released by American College of Radiology and Radiological Society of North America specifies standard X-ray procedures, such as routine chest X-rays and mammography, use relatively low levels of ionizing radiation [10]. As per the U.S Food and Drugs Administration report on radiation risks associated with CT, the radiation exposure from CT is higher than that from standard X-ray procedures, but the increase in cancer risk from one CT scan is still small. It is commonly thought that the extra risk of any one person developing a fatal cancer from a typical CT procedure is about 1 in 2,000 [11]. A detailed review on the Cancer statistics published by National Cancer Institute has concluded that the lifetime risk of dying from cancer in the U.S. population is about 1 in 5 [12]. A research work performed in U.S has estimated that approximately 29,000 future cancers could be related to CT scans performed and the largest contributions were from scans of the abdomen, pelvis, chest and head [13]. Researchers have commented on the widespread use of CT and other procedures that use ionizing radiation to create images of the body has raised concerns that even small increases in cancer risk could lead to large numbers of future cancers [14]. The report submitted to "National Research Council committee to assess Health Risks from Exposure to Low Level Ionizing radiation" (BEIR VII- Phase 2) has recommended that women are at a somewhat higher risk than men of developing cancer after receiving the same radiation exposures at the same ages [15]. The regulatory part of radiation containment from diagnostic imaging equipments is governed by the country specific regulatory authorities who develop the regulatory framework and standards.

Digital Radiography (DR) technologies have the advantage of a wide dynamic range compared to their film-screen predecessors, however, this

poses a potential for increased patient exposure if left unchecked [16]. The experimental research using exposure indicators to improve pediatric digital radiography pointed out that the manufacturers recommended Exposure Index (EI) as a measure of effective radiation doses has consistency related issues [17]. Research studies have estimated six days of life expectancy is lost due to medical diagnostic X-rays [18]. The estimates of effective dose from a diagnostic CT procedure can vary by a factor of 10 or more depending on the type of CT procedure, patient size and the CT system and its operating technique. A list of representative diagnostic procedures and associated doses as illustrated in Table 2 has been published by U.S Food and Administration website under the subject 'What are the radiation Risks from CT?' [19].

The implementation of Regulatory standards requires methodical Total Quality Management (TQM) approach [20]. A review article has suggested that there is an immediate need for undertaking research on 'Regulatory Compliance Related to Medical Devices Manufacturers and users [21]. A research work on "Diagnostic Laboratories - Are these Radiation Safe?" has identified number of business process gaps that have led to poor implementation of Regulatory Systems to contain the man-made ionizing radiation emanated from diagnostic imaging devices [22]. A research work on 'Regulatory Compliance On Radiation Safety Parameters with Chain of Diagnostic Centers in Tamil Nadu, India' has studied Regulatory compliance towards containing ionizing radiation and concluded that the regulatory compliance practices were found to be between Significant and High [23]. A research work on 'Analysis of Factors Influencing Regulatory Compliance to Contain Man-Made Ionizing Radiation from Medical Diagnostic Imaging Equipments in Corporate Hospitals", Tamil Nadu, India has concluded that corporate hospitals have shown superior level of compliance to contain radiation as per AERB regulatory guidelines [24]. This research work has further suggested similar studies to be extended in Government Hospitals within Tamil Nadu to understand compliance management system in practice and compare with corporate hospitals. Hence, this review has necessitated need for further research work to assess the effectiveness of regulatory system implementation in Government hospitals to protect people from excessive radiation.

1.4 Scope

The Government 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 Board for Hospitals and Healthcare Service Providers (NABH) has been included as a part of this research work.

1.5 Research Objectives

- To assess the current status of practices and maturity levels of processes implemented for meeting the Regulatory requirements stipulated by AERB for safeguarding people from the excessive radiation emanated from Diagnostic Imaging Equipments
- To analyze any significant difference exists on compliance related to radiation containment between Metro and Non-metro cities Government hospitals
- To study whether Radiological compliance and Patient Queue Size are related to each other.

Table 2. A list of representative diagnostic procedures and associated doses

Sl. no.	Diagnostic procedure	Average effective dose (mSv)
1	Chest X-ray (PA film)	0.02
2	Lumbar spine	1.5
3	I.V. urogram	3
4	Upper G.I. exam	6
5	Barium enema	8
6	CT head	2
7	CT chest	7
8	CT abdomen	8
9	Coronary artery	3
10	Coronary CT angiogram	16

2. MATERIALS AND METHODS

2.1 Research Hypothesis

The following research hypothesis have been developed and defined.

- **H_1:** There will be no significant difference in regulatory compliance score between Government hospitals housing Medical Imaging Equipments located in Metro cities and Non-metro cities.
- **H_2:** Patients queue size has positive impact on the compliance score.

2.2 Research Design

2.2.1 Sampling procedure

The universe has been defined using a detailed search with the help of "Google Search Engine", which has been conducted by the researcher through publicly available information sources. The search included List of registered X-Ray users, Government hospitals and AERB published X-Ray user's database respectively. The following open information sources on institutions using X-Ray equipments were identified.

- List of National Accreditation Board for Testing and Laboratories (NABL) / National Accreditation Board for Hospitals and Health care Providers (NABH) accredited hospitals in India.
- List of Government Hospitals and Equipments published by the respective states in India.
- Online portal (www.healthfrog.com) on registered hospitals in India.

From the above information sources and criterion, the universe has been defined. The Universe included Government hospitals having any one of Imaging Radiological Equipments (CT, X-Ray, BMD and Mammography). The licensed medical Diagnostic X-Ray facility within Tamil Nadu Government hospitals is 42, which stands as a definite universe of this research study. The samples have been derived accordingly through a methodical process. Initially, a formal communication has been sent through email addressing to all the Radiation Safety Officers across working for 42 Government hospitals in Tamil Nadu. The researcher has explained the objective of this research study and its intended benefits it can bring about for them in the communication and requested their active participation. Finally, 38 respondents who have agreed to participate in the research study were included as samples. List of institutions under each of strata, location (name of city) and call coordinates (email and contact information) were collected for this present research study. The cities covered in Tamil Nadu for sampling has been indicated in Table 3. The stratified random sampling technique has been adopted to identify the samples randomly from each stratum. A confidentiality agreement has been signed with all the participating hospitals. The researcher

Table 3. List of cities covered

Sl. no.	City name	Sl. no.	City name
1	Arupukottai	18	Madurai
2	Cheiyyar	19	Mannarkudi
3	Chennai	20	Mayiladuthurai
4	Coimbatore	21	Perambur
5	Dharmapuri	22	Periyakulam
6	Egmore	23	Royapettah
7	Kallakurichi	24	Salem
8	Kalpakkam	25	Sivagangai
9	Kanniyakumari	26	Srirangam
10	Karaikudi	27	Tambaram
11	Kilpauk	28	Theni
12	Kudangulam	29	Thirupathur
13	Thirupathi	30	Thiruvarur
14	Tirunelveli	31	Thiruvannamalai
15	Trichy	32	Tuticorin
16	Valajapet	33	Vellore
17	Vilupuram		

Table 4. Seven point measurement scale

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

has sent a detailed communication to Radiation Safety Officers on this study objective and explained the method of answering the questionnaire. This communication was then further followed-up multiple times by the researcher until the completed responses from 38 hospitals have been received.

2.2.2 Sample size

This research study has included responses received from 38 Government hospitals. The locations as specified in Table 3 across Tamil Nadu have been covered for this study.

2.2.3 Data collection techniques & instrument

The present research study collected the primary data through sample survey. Hence, only licensed Medical Diagnostic Equipment facility in Government hospitals listed and published by AERB have been included. The literature review on various research studies exhibited the country specific Atomic Energy Regulatory Board guidelines must be used for measuring the best practices and hence the researcher has base lined AERB guidelines for Medical Diagnostic Imaging in India and recommendations made by International Atomic Energy Agency. The researcher developed an instrument based on these standards and guidelines. In line with these standards, seven dependent variables covering Regulatory, Layout Engineering, Technical Competency, Human Safety, Operations Know-How, Monitoring Radiation Exposure and Management Commitment were identified for this study**.** The list of verification points under each parameter have been devised for assessing the practices and continuous adoption of standards. A total of 70 different questions were designed to capture the actual best practices followed by the Government hospitals addressing seven dependent variables. 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 [25] (Table 4).

2.2.4 Reliability of the instrument

The most popular reliability estimate has been given by Cronbach's Alpha [26,27]. 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 5) and Cronbach's alpha value as 0.943 (Refer Table 6). The Cronbach's alpha value estimated for the measurement scale used in this research is 0.943, which is well above the accepted limit of a minimum 0.80. Hence, scales used in the measurement tool have been construed as reliable.

Furthermore, the researcher has also estimated Cronbach's alpha for every item included in the measuring instrument and identified that alpha value was above 0.9 for each item (Table 7). This confirms that all the questions designed in the measurement tool can be included for this research study.

2.2.5 Sample sufficiency & sphericity test

The Kaiser-Meyer-Olkin (KMO) and Bartlett's test of sphericity is a measure of sampling adequacy, which is recommended to check the case to variable ratio for the analysis have been conducted. While KMO ranges from 0 to 1, the world wide accepted index is 0.6. Also, Bartlett's test of sphericity relates to the significance of study thereby exhibits the validity and suitability of the responses collected to the problem

Table 5. Scale reliability test summary

	Summary	Total size (N)	Percentage
Cases	Valid	38	100
	Excluded	0	0
	Total	38	100

Table 6. Cronbach's alpha test results

Cronbach's alpha	Number of items
0.943	44

being addressed through this study. In order to conduct factor analysis, Bartlett's test of sphericity must be less than 0.005.

The item-wise estimated Cronbach's Alpha test is shown in Table 7. The KMO and Bartlett's test results summary shown in Table 8 indicated the KMO measure of sampling adequacy has been estimated as 0.718, which is well within the acceptable limits. Hence, samples collected for this research study has been found acceptable for carrying out further analysis. Similarly,

Table 7. Item-wise estimated Cronbach's alpha test results

Question number	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Q1	172.34	123.042	0.628	0.941
Q2	172.82	125.235	0.552	0.941
Q3	172.97	125.972	0.747	0.941
Q4	172.76	121.645	0.697	0.941
Q5	172.16	122.461	0.782	0.939
Q6	172.5	123.23	0.597	0.941
Q7	172.21	126.009	0.486	0.942
Q8	172.82	124.695	0.602	0.941
Q9	172.16	122.191	0.807	0.939
Q10	172.5	122.797	0.631	0.941
Q11	172.76	128.564	0.261	0.943
Q12	172.61	125.218	0.502	0.942
Q13	172.71	123.454	0.582	0.941
Q14	173.11	128.475	0.213	0.944
Q15	173.39	123.543	0.444	0.943
Q16	172.92	124.885	0.557	0.941
Q17	172.16	122.028	0.744	0.941
Q18	172.42	122.737	0.637	0.941
Q19	172.95	123.132	0.752	0.941
Q20	172.79	122.387	0.484	0.943
Q21	172.5	123.176	0.601	0.941
Q22	172.13	123.955	0.766	0.941
Q23	172.92	128.021	0.231	0.944
Q24	172.53	122.094	0.687	0.941
Q25	172.87	125.144	0.617	0.941
Q26	172.08	122.399	0.898	0.939
Q27	172.18	119.722	0.844	0.938
Q28	172.08	122.399	0.898	0.939
Q29	172.34	125.420	0.485	0.942
Q30	173.29	126.373	0.419	0.942
Q31	173.05	123.186	0.238	0.952
Q32	172.08	122.399	0.898	0.939
Q33	172.05	124.722	0.844	0.941
Q34	172.08	122.399	0.898	0.939
Q35	173.11	128.475	0.213	0.944
Q36	173.39	123.543	0.444	0.943
Q37	172.92	124.885	0.557	0.941
Q38	172.16	122.028	0.744	0.941
Q39	172.42	122.737	0.637	0.941
Q40	172.95	123.132	0.752	0.941
Q41	172.79	122.387	0.484	0.943
Q 42	172.08	122.399	0.898	0.939
Q43	173.17	128.475	0.213	0.944
Q 44	172.51	123.176	0.601	0.941

Table 8. KMO and Bartlett's test summary

Kaiser-Meyer-Olkin measure of sampling adequacy		0.718
Bartlett's Test of Sphericity	Approx. Chi-Square	244.296
	df	21
	Sig.	0

Bartlett's test of sphericity has shown 'p" value as "zero", which signifies that responses collected using a structured instrument in this research study has been found appropriate and valid for analysis in line with the research objectives.

2.2.6 Content validity

The research questionnaire has been presented to a team of experts comprising Radiation Officers Association, serving as employees and consultants in various hospitals for a detailed review. The initial Questionnaire was designed with 54 questions covering all the seven parameters. It is after a comprehensive discussion and in-depth review by team of experts, the number of questions has been revised to 70. The distribution of questions in each parameter has been finalized in accordance with the requirements of study. In order to test the validity of responses, empirical checks have been performed at random by verification of practices as recommended by AERB guidelines. The empirical checks have provided sufficient evidences that the responses are in line with the actual practices followed.

2.2.7 Selection of appropriate statistical methods

As a pre-requisite for selection of appropriate statistics and tools, normality tests using compliance score has been performed and histograms have been drawn. The Skewness of distribution and kurtosis values has been derived using SPSS version 20. The estimated skewness (+0.794 and Kurtosis (+1.578) have shown that the data distribution is not normal. The histogram has shown bimodal distribution and does not form a bell-shaped normal distribution. Hence, the researcher has chosen Non-Parametric statistics in which Median was chosen as a central tendency. The hypothesis testing was done using Chi-square estimate and correlation test was performed using Spearman Rank Correlation.

2.2.8 Data confidentiality

The data collection for this research work has been kept confidential and safe throughout the entire Research Cycle. A confidentiality agreement has been signed with the respondents. The assurance to respondents has been provided by the researcher such that the data collected shall be used only for professional development, compliance and research study purposes. The research findings have been drawn up in such a way that no specific customer information and / or practices followed in that organization shall be published. This data confidentiality has been kept intact and only general information obtained from the respondents will be published to the limited group of stake holders having vested interest in this study.

3. RESULTS AND DISCUSSION

3.1 Regulatory

The data collected through the structured questionnaire from 38 Government hospitals to assess compliance with Regulatory guidelines has been processed and tabulated in "Regulatory Compliance Response Distribution" (Table 9). The number of responses under each scale and percentage distribution were estimated and shown in the below table and the plot. The Median was calculated for every question under Regulatory parameter and the overall Median for all the questions grouped under this variable.

The percentage distribution based on number of responses to every question has been plotted in a staked bar and presented (Fig. 1).

3.1.1 Interpretations on regulatory compliance

1. 68.42 percent of Government hospitals responded with "Complete Presence" of a practice in which Diagnostic Medical Equipments procurement happens only as per AERB guidelines. 26.32 percent of hospitals have asserted "Very High Presence" of a purchase system that ensures medical equipments compliance as per AERB guideline.
2. 90 percent of Government hospitals have agreed that the practice of registering the

facility with AERB is "Very Highly Present", while 5 percent have concurred the "Complete Presence" of this practice.

3. 89.47 percent of hospital tracks and updates the equipment history in e-Licensing Of Radiation Applications ("eLORA") online portal maintained by AERB and this practice is "Completely Present".
4. 75.01 percent respondents have agreed that process of facility approval and renewal by AERB as a system is "Completely Present", where as 18.95 percent responded with "Very High Presence" of this system.
5. 86.84 percent of the Government hospitals ensured that the process of displaying AERB approval as a system is "Completely Present".
6. The Median for complying to Regulatory requirements laid down by AERB is estimated at "6" - "Completely Present", which indicated that the government hospitals has a methodical system of ensuring every regulatory parameter is complied to the fullest intent.

3.2 Layout Engineering

The data table on number of responses against each question (Table 10) and percentage distribution along with estimated median for Layout Engineering parameter (Fig. 2) are shown below:

3.2.1 Interpretations on layout engineering compliance

1. 52.63 percent of Government hospitals responded with "Complete Presence" of practice in which Diagnostic Medical Equipments room lay out approval process is strictly adhered to as per AERB guidelines. 42.11 percent of Government hospitals have acknowledged for a "Very High Presence" of a system that drives, Diagnostic Medical Devices room lay out planning, review and approval as per the standard norms prescribed by AERB.
2. 39.42 percent of the Government hospitals have not compromised on installing Lead Door as a partition from X-ray room and conveyed that this practice is "Completely Present", while 58.42 percent have concurred "Very High Presence" of this practice.
3. 10.53 percent of hospitals construct X-ray room wall as per the guidelines of AERB and maintains the same standard in case of repair works. They have confirmed that this practice is "Completely Present" and room layout requirements are critically assessed even at the time of identification of site. 65.78 percent of hospitals ensure the "Very High Presence" of this practice, whenever new equipments are commissioned. 26.68 percent of the respondents have ranked this practice compliance as 'High".
4. 75.84 percent of hospitals firmly believed that construction of an independent Technical Room from where equipment Technician operates is not diluted and this practice is "Very Highly Present".
5. The Median for complying with Layout Engineering requirements in adherence to AERB standards is estimated at "6 – Complete Presence", which indicates that Layout Engineering requirements are well planned and executed.

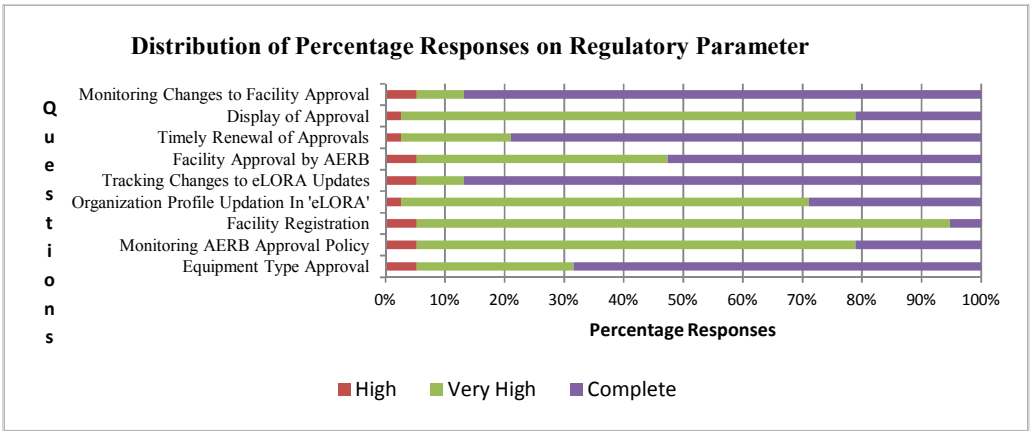

Fig. 1. Distribution of percentage of responses on regulatory

Table 9. Distribution of responses on regulatory compliance

Sl. no	Questions	Number of responses			Median
		High (4)	Very high (5)	Completely present (6)	
1	Equipment Type Approval	2	10	26	6
2	Monitoring AERB Approval Policy	2	28	8	5
3	Facility Registration	2	34	2	5
4	Organization Profile Updation in 'eLORA'	1	26	11	5
5	Tracking Changes to eLORA Updates	2	3	33	6
6	Facility Approval by AERB	2	16	20	6
7	Timely Renewal of Approvals	1	7	30	6
8	Display of Approval	1	29	8	5
9	Monitoring Changes to Facility Approval	2	3	33	6
		Overall median			6

.**Table 10. Distribution of responses on layout engineering**

Sl. no	Questions	Number of responses			Median
		High (4)	Very high (5)	Completely present (6)	
1	Equipment Layout Approval	2	16	20	6
2	Tracking Changes to Layout Approval	1	28	9	5
3	Commissioning Lead Door	1	22	15	5
4	Monitoring the Usage of Lead Door	3	22	13	5
5	Use of AERB Approved Material for Construction	9	25	4	5
6	Repair Work Material Usage Policy	22	10	6	4
7	Instituting Independent Technician Room	4	28	6	5
		Overall median			6

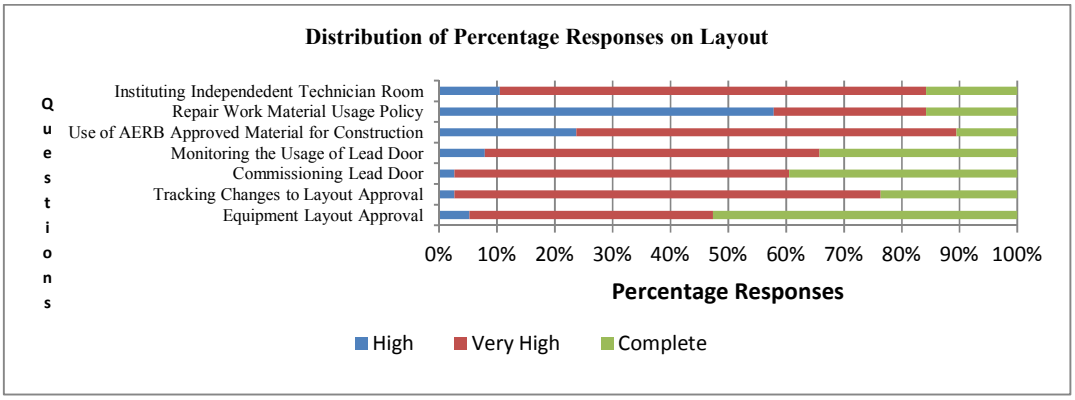

Fig. 2. Distribution of percentage of responses on layout

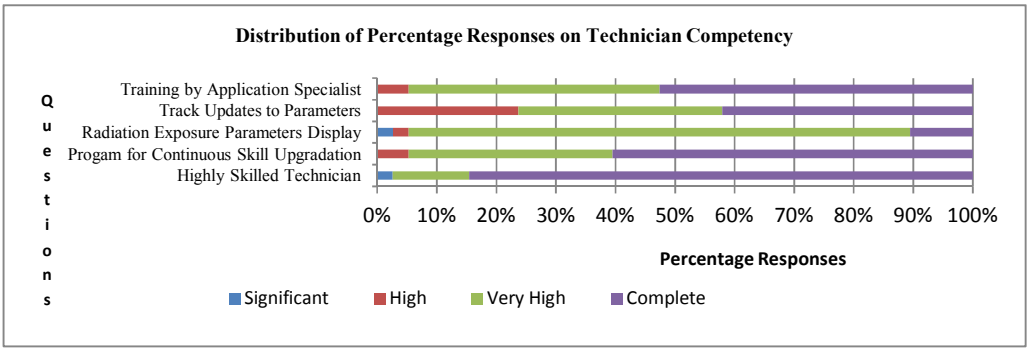

Fig. 3. Distribution of percentage of responses on Technician's competency

3.3 Technician's Competency

The distribution of number of responses against (Table 11) each question and percentage distribution along with estimated median (Above Fig. 3) has been illustrated below.

3.3.1 Interpretations on competency enhancement

1. 84.63 percent of Government hospitals responded with the "Complete Presence" of a practice where by only Qualified and Competent Technicians to operate Diagnostic Imaging Equipments are appointed. 12.11 percent of hospitals have opted "Very High Presence" of a management practice, for appointment of skilled technicians to effectively manage Diagnostic Imaging Equipments.
2. 85.68 percent of Government hospitals have responded on the practice of technician developing Standard Operating Procedure (SOP) for day-to-day handling of the equipment is "Completely Present". 11.68 percent have concurred "Complete Presence" of this practice where in Technician strictly adheres to Standard Operating Procedures (SOP) extracted from product manual as recommended by the manufacturer.
3. 53.89 percent of hospitals ensure that the practice of competency enhancement for Technicians, through application specialist and external sources exists with a rating "Completely Present". 42.47 percent of the hospitals expressed that training is an ongoing affair for continuous enhancement of skills and vouched for "Very High Presence" of this system.
4. The Median for Competency development of Technicians is estimated to be "6 - A Practice which is completely present", revealed that ongoing training by the manufacturer's application specialist and internal training programs are quite structured. It further resolved the fact that only competent and qualified Technicians have been appointed to operate Diagnostic Imaging Equipments.

Table 11. Distribution of responses on technician's competency

Sl. no	Questions	Number of responses				Median
		Significant (3)	High (4)	Very high (5)	Completely present (6)	
1	Highly Skilled Technician	1		5	33	6
2	Program for Continuous Skill Upgradation		2	13	23	5
3	Radiation Exposure Parameters Display	1	1	32	4	5
4	Track Updates to Parameters		9	13	16	5
5	Training by Application Specialist		2	16	20	6
			Overall median			6

Table 12. Distribution of responses on human safety

Sl. no	Questions	Number of responses			Median
		High (4)	Very high (5)	Completely present (6)	
1	Wearing TLD Badge During Scan	1	4	33	6
2	X-ray Room Door Closure Monitoring	6	24	8	5
3	Avoid Crowding at X-ray Room	2	17	19	6
4	Usage of Lead Aprons for Mobile X-ray	2	30	6	5
5	Equipment Quality Assurance Test at Installation	2		36	6
			Overall median		6

Table 13. Distribution of responses on operations know-how

Sl. no	Questions	Number of responses				Median
		Significant (3)	High (4)	Very high (5)	Completely present (6)	
1	Collimator Usage	1	1	3	33	6
2	Protecting Abdomen while Scanning Pregnant Woman		2		36	6
3	Storage of TLD Badge when not in Use		1	12	25	6
4	Signage's and Radiation Stickers		13	24	1	5
5	Usage of Pediatric Protocols		2	27	9	5
6	Maintenance of Environmental Conditions		2		36	6
			Overall median			6

3.4 Human Safety

The distribution of number of responses on compliance to human safety parameters has been compiled (Table 12) and their cumulative percentages are shown in Fig. 4.

3.4.1 Interpretations on human safety

1. 86.89 percent of Government hospitals follow the practice of wearing TLD badges while operating Diagnostic Imaging Equipment and revealed that this system is "Completely Present". 10.21 percent of hospitals Technicians confirm that TLD Badge usage at the chest level is a practice which is always "Very High Compliant".
2. 21.79 percent of the government hospitals have agreed that the practice of X-ray room door closure and monitoring while scanning patients is "Completely Present", 62.68 percent expressed "Very High Presence" of this practice and 15.53 percent has concurred the "High Presence" of this practice.
3. 51.89 percent of hospitals agreed on the process of creating awareness towards precautionary measure for avoiding excessive radiation exposure among public is continuous and rated as "Completely Present". Furthermore, 44.32 percent hospitals confirmed that this practice is "Very Highly Present" and 3.79 percent follow this practice very meticulously for establishing a "Complete Presence".
4. 81.68 percent of respondents have agreed that the process of using Lead Aprons while Mobile X-ray machines scanning is "Very Highly Present". 5.53 percent of the Government hospitals have this practice "Highly Present" and 12.79 percent of the respondents rated as a system which is "Completely Present".
5. A vast majority 96.84 percent of Government hospitals ensure that the process of conducting QA tests both at the time of installation and every 2 years after the commissioning, for certifying the "fitness" as a practice has been followed without any compromise and such practices are always "Completely present".
6. The Median for complying with best practices on controls exercised to protect human from excessive radiation exposure is estimated at "6 - Completely Present", which indicated that extremely high priority is attached on safeguarding employees working in hospitals and public who comes for availing the services.

3.5 Operations Know-How

It has been observed from above Table 13 which exhibited the number of responses against each question and percentage distribution along with estimated median for operations 'Know-How" parameter for assessing the Operations "Know-How" compliance response distribution. The graphical representation showing responses on compliance towards operations "know-how" distribution as a percentage in each rating scale were represented in Fig. 5 for distribution of Compliance practice on operations "know-how".

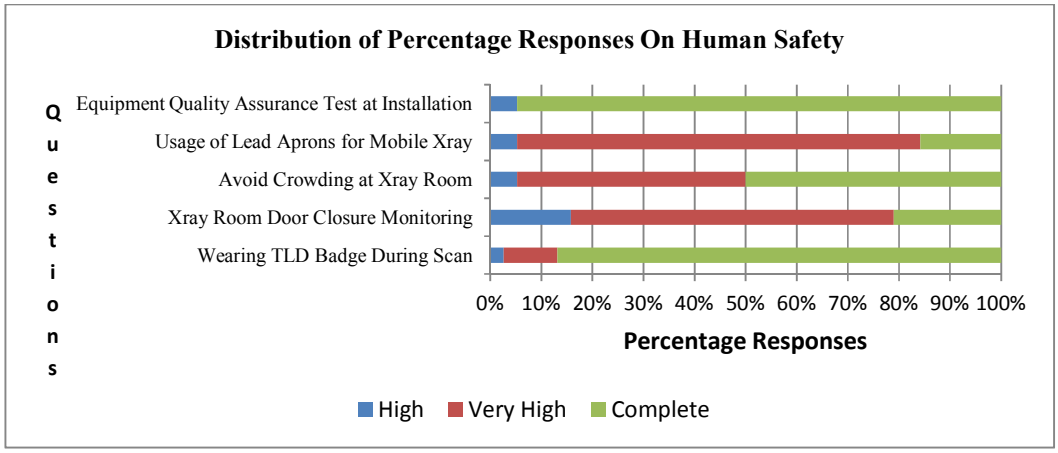

Fig. 4. Distribution of percentage of responses on human safety

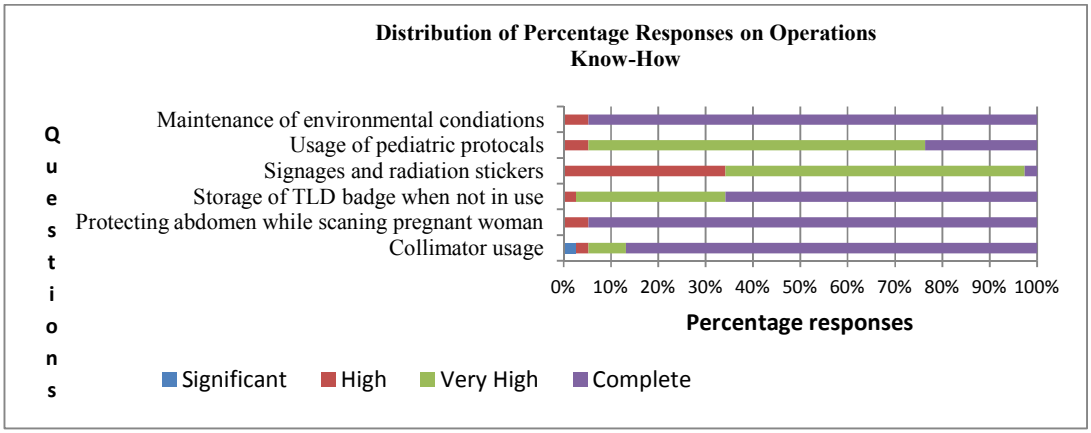

Fig. 5. Distribution of percentage of responses on operations know-how

3.5.1 Interpretations on operations "know-how"

1. 86.53 percent of technicians working in Government hospitals have agreed that manipulating Collimeter for adjusting radiation exposure is a critical practice and as a system this is "Completely Present". Moreover, 10.21 percent of hospitals technician opined that Collimeter usage practice is "Very Highly Present".
2. 94.21percent of Government hospitals has in complete agreement on the usage of Aprons for covering abdomen when scanning pregnant woman patients so as to prevent radiation exposure in abdomen. Also, this practice is "Completely Present". In furtherance, 5.79 percent of technicians agreed that apron usage is mandatory for making abdomen and this process is "Very Highly Present".
3. 65.11 percent of technicians are well aware of the requirements to preserve TLD badge and control badge outside the X-ray room, when not in use and compliance is rated as "Completely Present". In addition to that, 31.21 percent of the technicians agreed that preservation of TLD badges as a practice is "Very Highly Present". Also, 3.68 percent of responses from technicians revealed that TLD badge preservation practice is "Highly Present".
4. 64.63 percent of hospitals believe that display of radiation stickers and other direction signage's have improved the compliance to contain radiation exposure by establishing a" Very Highly Compliant" system. In furtherance, 32.11 percent have agreed that visual control system is "Highly Present" that directs those who accompany the patients to be away from radiation exposure.
5. A vast majority of 76.84 percent of the Government hospitals ensure that the process of using pediatric protocols is very strictly complied with in order to take extra care on children when they are subjected for scanning. Moreover, this requirement is compliant fully.
6. 65.05 percent of technicians confirmed that the temperature and humidity inside X-ray room and Technical room are monitored and maintained as per the manufacturer's recommendation. This practice is "Completely Present" in order to facilitate continued usage of equipment without any hindrance until the expiration of X-ray tubes shelf life. 33.16 percent of hospital technicians agreed that this practice is "Very Highly Present". 1.79 percent of technicians felt that the system of monitoring temperature and humidity is "Highly Present" for leveraging better life of the equipment.
7. The estimated median for compliance relating to "Operations Know-How", which reflects the hospital technicians day-to-day ability to maintain the equipment is at, "6 - Completely Present'.

3.6 Monitoring Radiation Exposure

The compliance on best practices practiced towards monitoring radiation exposure has been compiled based on the number of responses and presented in Table 14. The cumulative percentage distribution has been plotted and graphically shown in Fig. 6.

Table 14. Distribution of responses on monitoring radiation exposure

Sl. no	Questions	Number of responses			Median
		High (4)	Very high (5)	Completely present (6)	
1	Timely Submission of TLD Badge for Analysis (Quarterly)	1	1	36	6
2	Monitoring the Dosage Levels of Technician	2		36	6
3	Performing Periodical QA test (Every 2 Years)	1	12	25	6
4	Managing Exposure Incidents	13	24	1	5
5	Evaluating AERB Approved Service Providers	2	27	9	5
		Overall median			6

Table 15. Distribution of responses on top management commitment

Sl. no	Questions	Number of responses			Median
		High (4)	Very high (5)	Completely present (6)	
1	Appoint Qualified Suppliers for QA Test	2		36	6
2	Understand QA Test Outcome and take CAPA	1	1	36	6
3	Fund for Stocking Adequate Aprons	2		36	6
4	Organize Experts Training for Technician	1	12	25	6
5	Budget for Third Party Apron Testing	13	24	1	5
6	Appoint Full-time RSO	2	27	9	5
7	Engage Service Providers for Equipment Service Contracts	2		36	6
		Overall median			6

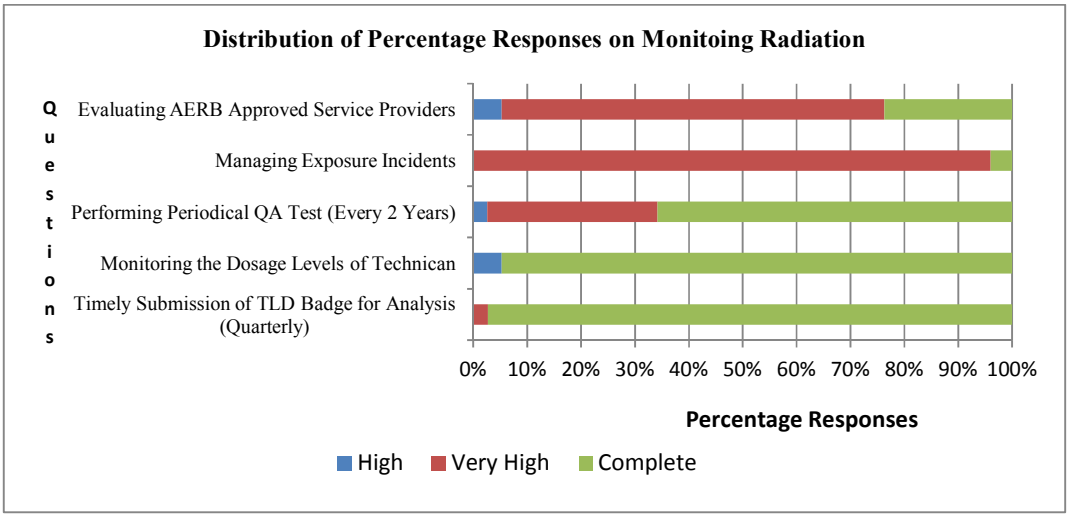

Fig. 6. Distribution of percentage of responses on monitoring radiation

3.6.1 Interpretations on radiation exposure monitoring

1. 97.82 percent of Government hospitals responded with the “Complete Presence" of practice in which TLD badges used by Technicians are rotated on a quarterly basis and sent to AERB authorized third party test labs for measuring the exposure to radiation. 1.18 percent of Government hospitals have asserted that “Very High Presence" on a system of testing TLD badge at 3rd party AERB authorized lab exists.
2. 94.95 percent of Government hospitals practices a system in which the test reports on radiation exposure is reviewed to see whether actual exposure is within the stipulated norms over a period of 5 years. This practice is extremely critical as the technicians also get exposed to radiation and this process has been found to be "Completely Present". 4.15 percent of the hospitals have expressed that Radiation exposure monitoring and invoking incident management system practices is ‘Very High” compliant.
3. 64.74 percent of the Government hospitals confirmed that Quality Assurance testing for the diagnostic imaging equipment is done at the completion of equipment installation and on a regular basis, once every 2 years. This is a very critical requirement to keep the equipment fully fit for use and operation. Moreover, this process practice is "Completely Present". 31.42 percent responses have favored the existence of ‘Very High” compliant practice.
4. 96.84 percent of Government hospitals expressed that a system of reviewing radiation exposure results on a quarterly basis using third party test report is "Very Highly Present". This is based on the cumulative dosage for a specified period of 5 years. Also, the technician would be released on a compulsory paid holiday, if radiation exposure is found to be more than the specified levels on any given year.
5. The Median for complying with Radiation Exposure Monitoring and invoking incident management is estimated with a value of "6- A practice that is Completely Present".

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. The appointment of full-time Radiation Safety Officer (RSO), who spear heads this change has been reported to be completely present in all the Government Hospitals studied. The distribution of number of responses is shown in Table 15 and cumulative percentage distribution is shown in Fig. 7.

3.7.1 Interpretations on top management commitment

1. 96.74 percent of hospitals confirmed that every Diagnostic Imaging Equipment has been bought only as per AERB guidelines. The policy decision by Government

Hospitals is that at any point of time, refurbished equipments will not be purchased. The practice of buying medical devices as per the AERB guidelines makes the process compliance as “Completely Present".

2. 94.79 percent of respondents have responded with a "Complete Presence" of a system in which the equipment suppliers are made to conduct QA test at the time of installation and hand-over. The periodical conduct of QA test at least once in 2 years is also done by equipment maintenance suppliers.
3. Training the Technicians on efficient operation of the equipment by manufacturer’s application specialist and periodical training sessions by experts in the respective field has been practiced as a strategy in order to continuously enhance the competency. 64.68 percent of responses have expressed that this practice is "Completely Present", 29.79 percent have rated this as "Very High Presence" and 5.53 percent have satisfied with "High Presence".
4. The appointment of Radiation Safety Officer (RSO) as a full time employee, in order to effectively implement and monitor AERB guidelines has been complied by all Government hospitals in true spirit. 94.74 percent of respondents have rated this practice as “Completely Present".
5. It has been observed that Government Hospitals as a policy cover every medical device with a minimum period of 2 years warranty and 5 years Comprehensive Maintenance Contract (CMC) at the time of purchase. This ensures that for a minimum period of 7 years, the equipment is fully protected for uptime, periodical service, repair maintenance and QA test. This was obvious as 94.74 percent of hospitals confirmed that this practice is "Completely Present".
6. The overall Median for Top Management Commitment was estimated to be “6-Complete Presence”, which indicated that, a very highly committed Top Management over sees the compliance requirements stipulated by AERB in managing all Medical Devices throughout its life cycle.

3.8 Hypothesis Testing

In order to test the existence of significant differences with regard to regulatory compliance between Government hospitals located in Metro and Non-metro cities, Chi-Square test has been adopted by the researcher(s). The hypothesis to understand this relationship titled “*No Significant difference exists between Metro and Non-metro zone Government hospitals on compliance to contain radiation*” has been framed. The median compliance score between metro and non-metro hospitals has been compiled and tabulated (Table 16).

The Chi-Square test has been performed at 95 percent confidence level with alpha value “0.05”. The test results have shown ‘Chi-Square” value as 0.109547, degrees of freedom at 6, and “P” value 0.9999. The estimated “P” value (.99997) is found to be greater than alpha value (0.05). The smaller Chi-square value indicates that the variation between metro and non-metro group data is not significant. Hence, the null

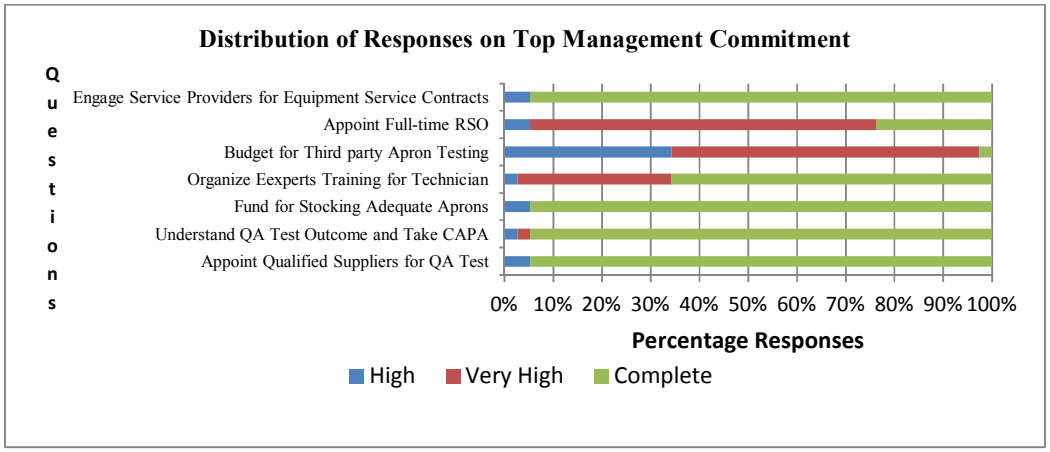

Fig. 7. Distribution of percentage of responses on top management commitment

Table 16. Median compliance score for chi-square estimation

Sl. no	Compliance parameter	Metro	Non-metro	Total
1	Regulatory	5	6	11
2	Layout	5	5	10
3	Competency	6	5	11
4	Safety	6	6	12
5	Know How	6	6	12
6	Exposure Monitoring	6	6	12
7	Commitment	6	6	12
	Total	40	40	80

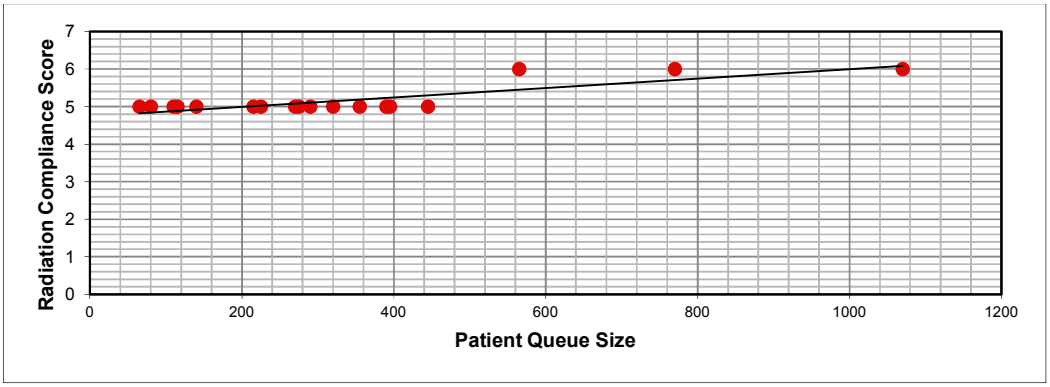

Fig. 8. Correlation between patient queue size and regulatory compliance

hypothesis is not rejected. This results support the argument assumed by researchers that there will be no significant differences between metro and non-metro Government hospitals. Hence it is concluded from the analysis that there is a no significant difference in compliance score of Government hospitals in metro cities and non-metro cities.

3.9 Relationship between Patient Queue Size and Compliance Score

The relationship between Patient Queue Size and Compliance score has been tested using Spearman Rank Correlation Co-efficient with Alpha value of 0.05 at 95 percent confidence interval. The Correlation Co-efficient (Rho) was found to be - 0.095. This indicates a very weak negative correlation between Patient Queue size and Compliance Score which is insignificant as inferred from 'P' value of 0.5712, higher than the alpha value. Hence, the Null Hypothesis (Patient Queue Size has a Positive impact on Compliance Score) has been rejected.

3.10 Implications

The detailed analysis of data collected from Government hospitals to study the current status of regulatory compliance in order to protect the hospital staff and public from excessive man-made ionizing radiation has shown superior compliance in all the seven dependent variable studied. The compliance score of all seven dependent variables is shown in Table 17.

The superior compliance has been well achieved in every aspect of regulatory requirements stipulated by AERB by all the Government hospitals by appointing Radiation Safety Officer, who leads this change initiative. The superior Top Management commitment and appointment of full time Radiation Safety Officer for ensuring AERB compliance have contributed for this superior compliance score. The compliance to AERB guidelines for continued maintenance of Radiological Imaging Equipments that emanates radiation, in all the seven different parameters studied revealed that more than adequate controls are in place. This illustrates that Government Hospitals housing Radiological Imaging Equipments maintain a very high level of systems and process practices that are fully compliant with AERB requirements. This provides complete confidence in the minds of patients on superior commitment to protect safety and quality scanning. The Chi-Square test has established insignificant difference in regulatory

Table 17. Comparison of radiation compliance score

Sl. no	Parameter	Compliance score (Median)	Scale description
1	Regulatory	5	Very High Compliant
2	Layout Engineering	6	Complete Presence
3	Technician Competency	6	Complete Presence
4	Human Safety	6	Complete Presence
5	Operations Know-How	6	Complete Presence
6	Radiation Exposure Monitoring	6	Complete Presence
7	Top Management Commitment	6	Complete Presence

compliance score between Government Hospitals located in Metro and Non-metro cities housing imaging equipments. The Spearman Rank Correlation has established a very weak and insignificant relationship between patient queue size and regulatory compliance. These supportive evidences and statistical analysis concluded that the entire research objective drawn-up in this research study has been successfully tested and appropriate inferences drawn.

4. CONCLUSION

Based on the detailed analysis and statistical inferences of this research study, it has been concluded that government hospitals have shown a very high level of compliance in all the seven variables analysed in this research study. Furthermore, all the seven dependent variables taken in this research study have shown superior compliance on the higher side of measurement scale between 5 and 6 on a 6 point scale. This illustrates that there has been significant importance and priority assigned to all the functions of Government hospitals towards radiation control measures implementation. In furtherance, this research study further recommends similar research work to be extended in corporate hospitals, Government Hospitals, Chain of diagnostic centers and Private Diagnostic centers in other states of India, to understand the compliance management system in practice.

It is to be noted that Diagnostic Imaging equipments use Picture Archival and Communication System (PACS) software, which constructs and displays scanned images for diagnosis purposes. However, these images are typically stored in multiple external storage devices such as Pen Drives, Internal and External Hard Disk Drives, DVD drives and other computer systems and accessories connected through intranet in a Local Area Network (LAN) environment. The patient information and scanned images are highly sensitive, and it is the complete responsibility of hospital management to protect confidentiality, integrity and availability by deploying appropriate information technology security systems and control measures. This necessitates the further need for researching the high tech global practices in information security prevalent in monitoring hospitals for safeguarding Patient Health Information (PHI).

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable. Though this research is qualitative in nature, an agreement has been signed with the respondents and the same has been included in the manuscript.

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COMPETING INTERESTS

Author has declared that no competing interests exist.

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