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Analysis of Regulatory Compliance on Radiation Safety Parameters with Chain of Diagnostic Centers in Tamil Nadu, India

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Authors' contributions

This work was carried out in collaboration between both authors. Author RR designed the study, conducted literature searches, wrote the protocol, performed the statistical analysis and wrote the manuscript. Author PRRK has conducted a detailed review and provided strategic direction for successful completion of this research study.

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ABSTRACT

Aims: To evaluate compliance against Atomic Energy Regulatory Body guidelines in India with chain of diagnostic centers, aimed at protecting the health of people while using human made ionizing radiation. To assess whether revenue, patient queue size and Quality System accreditation influence the Regulatory compliance.
Study Design: Descriptive Research Design was used to study the existing practices.
Place and Duration of Study: 107 chain of diagnostic centers, which houses the diagnostic imaging equipments that emanates radiation, which needs regulatory compliance were studied. This study was conducted in 25 identified cities across Tamil Nadu, in India between April 2016

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and June 2017.
Methodology: We included 65 chains of diagnostic centers accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) and 42 Non-NABL diagnostic centers. The Radiologists and Technicians were the point of contacts for primary data collection through a structured questionnaire. The compliance to regulatory guidelines was assessed using a 7 point scale, based on the existing practices followed. There were 70 questions covering Regulatory, Layout Engineering, Technician Competency, Human Safety, Operations Know-How, Radiation Exposure Monitoring and Top Management Commitment included in this study. Non-Parametric statistics was used to perform the analysis.
Results: The probability distribution was estimated using "mode" as a measure of compliance. The compliance on 7 parameters studied has shown, Regulatory (3, Significant compliance), Layout Engineering (3, Significant compliance), Technician Competency (4, High Compliance), Human Safety (4, High Compliance), Operations Know-How (3, Significant Compliance), Monitoring Radiation Exposure (4, High Compliance) and Top Management Commitment (4, High Compliance). Wilcoxon Rank Sum test has shown a '*P*' value of .083 @ 95 percent confidence interval established no difference in compliance between NABL and Non-NABL diagnostic centers. Spearman correlation co-efficient (Rho +0.12 and '*P*' value, .43) has established a positive weak and insignificant relationship between Revenue and Compliance and negative weak and insignificant relationship (Rho -.093, '*P*', 0.52) between patient queue size and compliance.
Conclusion: The chain of diagnostic centers did not pose any risk of radiation leakage supported by significant and high compliance scores across all parameters studied. The NABL accreditation did not influence the compliance. Revenue and Patient queue size did not establish significant relationship on compliance. Similar studies can be initiated with Government Hospitals, Corporate Hospitals and Private Diagnostic centers in other states of India.

Keywords: Chain of diagnostic centers; atomic energy regulatory body; handmade ionizing radiation safety; total quality management; radiation compliance parameters.

1. INTRODUCTION

1.1 Background of the Problem

The Global Healthcare expenditures are projected to reach USD 8.7 trillion by 2020 (Source, 2017, Global Healthcare outlook report published by Deloitte) driven by rising chronic disease, rapid urbanization, sedentary life styles, changing diet and rising obesity levels. The investment in preventive health is seen as an asset to lead a healthy life and specific areas of investment covers adult & child immunization policies, disease screening and healthcare associated infection prevention policies and programs. The Healthcare industry in India is expected to touch USD 280 billion by 2020 (Source: Frost & Sullivan, LSI Financial Services, Deloitte, Tech Sci Research, 2016). It has been estimated that additional 3 million beds are needed for India to achieve the target of 3 beds per 1000 people according to a vision set by Government of India. In order to accomplish this vision, about 200 billion USD is estimated to be invested in medical infrastructure creation including setting up of Diagnostic Laboratories across Tier II and Tier III cities. The Computed Tomography (CT) Scanner, Digital X-ray machine, Mammography and Bone Mineral Density (BMD) meter are often procured by Diagnostic Centers for commercial operations. These equipments use manmade ionizing radiation for creating the image of organs being scanned, which posses' inherent risk of exposure to excessive radiation. The diagnostic centers prefer buying refurbished equipments due to their availability at substantially lower cost and offer quality scanned images similar to the new equipments. India is a larger consumer of refurbished equipments imported globally and their distribution is controlled by the regulator, Atomic Energy Regulatory Body (AERB). There were no restrictions on the age of refurbished equipments by AERB until 2015 and the pre-requisite was to implement and maintain controls specified by AERB for containing radiation. The revised regulatory norms circulated by AERB, reference Number AERB/RSD/MDX/Service Agencies - RR/2015193 dated 18 September 2015, states that "the Pre-owned medical Diagnostic X-ray equipment, which is more than seven years old, shall not be imported in the country." This restriction has made many business entities to shutdown their operations and look for alternative business to survive. This has intrigued the researcher in conducting a research work on studying the compliance towards regulatory parameters set by AERB for the existing imaging equipments installed and used by diagnostic centers, which are more than 7 years old.

1.2 Research Question

Do the Chain of Diagnostic Center's housing medical imaging equipments, which have inherent risk of manmade radiation exposure, follow the practices laid down by AERB on regular basis for radiation containment?

1.3 Literature Survey

Radiation is used in medicine for both diagnostic and therapeutic purposes. Irrespective of the level of healthcare system, medical use of radiation increases yearly as the benefits of procedure become more widely disseminated. The medical use of ionizing radiation remains a rapidly changing field, stimulated by high level of innovation by equipment manufacturer and suppliers. The physicians, technicians, nurses and others involved constitute the large single group of workers occupationally exposed to manmade sources of radiation. The exposure to radiation is measured in dose limits and internationally the threshold limit is set at 100 mSv (millisievert), cumulative for a period of 5 years.

The estimated radiation risks potentially associated with full body CT screening was comprehensively studied and results published [1]. The monitoring of radiation exposure and the careful use of medical equipments emanating radiation is governed by the country specific Regulatory body and in India; Atomic Energy Regulatory Body has been assigned with this responsibility. A detailed research on the effect of radiation when performing mass screening using CT colonography was conducted and countermeasures were discussed adequately [2]. The clinical audits have found that inappropriate use of CT at least 25 percent of the scans. The risk of cancer from diagnostic x-rays based on the study performed in 14 different countries revealed that there is an imminent need for reducing the dose level used for X-ray [3]. The National Research Council has prepared a detailed report on the relationship between ionizing radiation and human health to advise U.S. Government [4]. The health risks from exposure to low levels of Ionizing radiation have been detailed in this report with recommended policy level changes for protecting patients and technicians from radiation. The effect of unjustified CT examinations in young patients has been studied and the concerns related to medical experts recommending not so needed CT scan were narrated [5].

The United Nations Scientific committee in their report on 'Sources and Effects of Ionizing Radiation' has comprehensively discussed early health effects of radiation with specific reference to acute radiation syndrome on emergency workers and late health effects in Leukemia and Solid cancers [6]. The International Atomic Energy Agency has established a detailed standard and guideline for inspection of radiation sources, which is made available for public and organization use [7].The general principles of lowering radiation dose, the basic physics that impact radiation dose, and specific CT integrated dose-reduction tools focused on the pediatric population has been reviewed and published [8]. An evidence based study has revealed that there is no substantial gain in the whole body CT screening as against the routine care, though there is a substantial increase in cost associated with it [9]. A report on radiation risk potentially associated with Low-Dose CT screen of adult smokers, with regular annual CT scanning has shown tangible risk [10].

A review on the nature of CT scanning and its main clinical applications, both in symptomatic patients and, in a more recent development, in the screening of asymptomatic patients has revealed that the recommendations for CT scan is on the rise [11]. The modern technological developments in CT and dosimetry permit patient doses to be determined in a way that better represents the risk to the patient [12]. Computer simulations are widely used to estimate effective doses from CT examinations [13]. A research study on the awareness of radiation does and potential risks involved among patient, physician and radiologist brought out that very minimal awareness was found to be seen and that raises serious concern [14]. Hence there is a need to establish and deal balance between radiation dosage and image quality which is adequate for the clinical purpose with the minimum radiation dose [15].

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 [16,17]. A research paper titled "Diagnostic Laboratories - Are these Radiation Safe?" has proposed further research on Regulatory Compliance with Chain of Diagnostic Centers. So, this review has necessitated need for further research work to assess the effectiveness of regulatory system implementation in chain of diagnostic centers to protect people from excessive radiation [18].

1.4 Scope

The Chain of Diagnostic Laboratories in Tamil Nadu, India registered with AERB for offering Diagnostic Scan services using imaging devices has been scoped for this research. The diagnostic laboratories accredited under 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 chain of diagnostic centers in order to comply with the Regulatory and operational requirements stipulated by AERB
- To assess whether significant difference in compliance exists between NABL and Non-NABL diagnostic chain
- To find out whether there is a significant relationship exists between "Revenue Vs Compliance" and "Patient Queue Size Vs Compliance".

2. MATERIALS AND METHODS

2.1 Research Hypothesis

The Diagnostic centers pursue NABL accreditation as a means of establishing credibility in the market place and use this certification as a differentiator to win over the competition. Hence the researcher has formulated a hypothesis to test whether NBAL and Non-NABL chain of diagnostic centers differ in their approach towards regulatory requirements implementation and compliance.

H1: There will be no difference in regulatory compliance between NABL accredited and Non-NABL Chain of Diagnostic Centers.

The regulatory system implementation requires top management commitment and substantial investment in identified areas toward implementation of new systems, acquiring better infrastructure, testing the fitness of equipments and technicians skill development program. Hence the researcher has chosen to test whether revenue has an impact on high compliance. So, the second hypothesis is stated as below:

H2: Revenue has a positive impact on the compliance

The diagnostic chain promotes their existence through campaigns, advertisements and free check-ups in order to increase the flow of patients. Hence, it is assumed that regulatory compliance can positively influence queue size. Accordingly the third hypothesis is established to test whether patient queue size has a correlation with compliance.

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 Chain of Diagnostic Centers, AERB published X-Ray users and NABL accreditation board data base respectively. The Universe included chain of diagnostic laboratories having any one of Imaging Radiological Equipments (CT, X-Ray, BMD and Mammography). The researcher reviewed them on the basis of their license. The licensed chain of medical Diagnostic X-Ray facilities within Tamil Nadu is 214, which stands as a definite universe of this research study. Finally, 107 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 institutions using Diagnostic Imaging Equipments. The data collection has been carried out on institutions adhering to best

Table 1.

0	1	2	3	4	5	6
No practice exist	Marginal presence	Moderate presence	Significant presence	High presence	Very high presence	Complete presence

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.

2.2.3 Data collection instruments

The present research study collected the primary data through sample survey. Hence, only licensed Medical Diagnostic Equipment facility listed and published by AERB have been included. 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 [19] (Table 1 above).

2.2.4 Reliability of the instrument

The reliability refers to the extent to which an experiment, test or any measuring procedure yields the same results on repeated trials [20]. The most popular reliability estimate has been given by Cronbach's Alpha [21]. 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 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 through structured questionnaire from 107 respondents were grouped under each variable considered for this study and the distribution of responses against each measurement scale has been tabulated for further analysis. The distribution of responses in terms of number of responses under each measurement scale for each question on "Regulatory Parameter" along with the mode (the central tendency) is tabulated in Table 4.

It was quite evident from Table 4 that day to day practices followed across all diagnostic centers studied have exhibited significant level of compliance on most of the Regulatory guidelines mandated by AERB. The main focus area for adoption of regulatory guideline has been identified as the decision to buy and commission AERB approved diagnostic imaging equipments.

3.2 Layout Engineering

The layout engineering guideline provides adequate measures for protecting radiation emanated from the equipment during scan, through designing proper layout and construction of appropriate walls. The distribution of responses for various controls under layout engineering has been grouped and shown in Table 5. This distribution shows that compliance to obtaining AERB approval for equipment layout gains significant attention and compliance to process practices towards all other allied measures are considered at moderate level.

Almost 100 percent respondents have agreed on the significance of compliance to layout approval process and tracking changes to layout structure. The compliance to practices towards establishing layout compliance was found to be above ‘Significant Level”. The diagnostic laboratories have not compromised on Lead door commissioning as observed from Fig. 2 revealed that 100 percent “High” level” of compliance existed.

3.3 Technician’s Competency

It was evident from the Table 6, “Distribution of Responses on Technician Competency” that the compliance to sourcing and appointing highly skilled technicians as a practice is at marginal level and this gap is very well compensated through continuous skill upgradation. The deployment of key drivers for technician’s productivity and quality work could be well understood from higher level compliance shown in this study.

It was observed from Fig. 3 that more than 80 percent of respondents have expressed only moderate level compliance on system

Table 4. Distribution of responses on regulatory

Sl. No	Questions	Responses				
		Moderate (2)	Significant (3)	High (4)	Very high (5)	Mode
1	Equipment Type approval		107			3
2	Monitoring AERB Approval Policy		104	3		3
3	Facility Registration		104	3		3
4	Organization profile updation in 'eLORA'		94	13		3
5	Tracking changes to ‘eLORA’ updates	2	105			3
6	Facility Approval by AERB		107			4
7	Timely Renewal of approvals			99	8	4
8	Display of approval		2	92	13	4
9	Monitoring changes to facility approval			94	13	4

Table 5. Distribution of responses on layout engineering

Sl. No	Questions	Responses			
		Moderate (2)	Significant (3)	High (4)	Mode
1	Equipment Layout approval		107		4
2	Tracking changes to layout approval		97	10	4
3	Commissioning Lead door			107	5
4	Monitoring the usage of lead door	107			2
5	Use of AERB approved material for construction	107			2
6	Repair work material usage policy	104	3		2
7	Instituting independent technician room	92	15		2

Table 6. Distribution of responses on technical competency

Sl No	Questions	Responses						Mode
		Marginal (1)	Moderate (2)	Significant (3)	High (4)	Very high (5)	Complete (6)	
1	Highly skilled technician	85	22					2
2	Program for continuous skill upgradation						107	6
3	Radiation exposure parameters display					107		5
4	Track updates to parameters				101	6		4
5	Training by application specialist			6	78	23		4

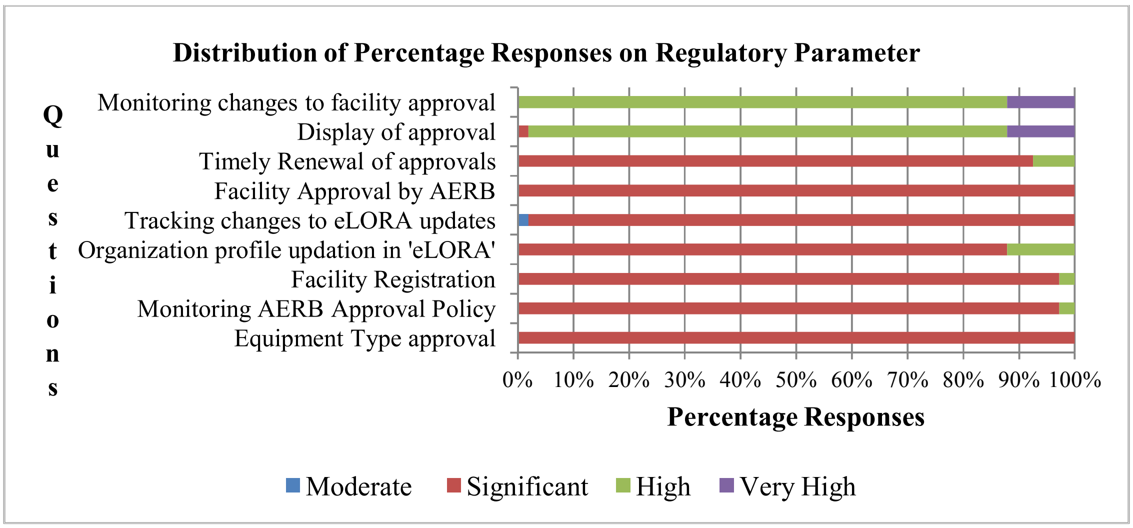


Fig. 1. Comparison of percentage responses for regulatory requirement

implementation towards sourcing and deploying highly skilled technicians. Though this sounds risky, the diagnostic centers management seems to have compensated this through planning and execution of methodical skill development program which was expressed as a practice completely followed by 100 percent of respondents. The training of technicians by equipment manufacturer's software application specialists augment well for continuous skill upgradation and competency enhancement.

3.4 Human Safety

Ensuring safety of people who work with imaging equipments is a key requirements stipulated by the regulator and the technicians are expected to wear Thermo luminescent Dosimeter (TLD) badge while performing scan. The compliance on wearing TLD badges, X-ray room door closure and equipment Quality Assurance testing are summarized in Table 7. More than 80 percent of the respondents have agreed that regulator guidelines for ensuring compliance with Human safety parameters are always high (Fig. 4).

3.5 Operations Know-How

The technician's knowledge on functioning of imaging equipment and a detailed understanding of the technology involved in scanning process will ensure high quality imaging with almost zero risk of excessive radiation exposure. The responses towards Operations Know-How compliance are summarized in Table 8.

The responses on Operations Know-How have clearly shown that significant compliance is seen on the usage of collimeter, which helps navigating required X-ray exposure with more than 90 percent responses centered at higher compliance (Fig. 5). Almost 100 percent of the respondents have agreed that more than significant compliance is shown in protecting abdomen of pregnant women when CT scan is performed. The analysis results have shown that extreme care is undertaken for protection of TLD badges when it is not used, with 100 percent responses favoring significant compliance. However, maintaining the recommended temperature and humidity (90 percent responses provided moderate compliance Fig. 5), Pediatric protocols usage (100 percent responses rated moderate compliance) and signage's / stickers for creating awareness (almost 90 percent of respondents have evaluated for moderate compliance, Fig. 5) on impacts due to radiation exposure have received marginal to significant compliance levels.

3.6 Monitoring Radiation Exposure

The technician who works with imaging equipment is exposed continuously to radiation and AERB has specified 100 mSv (millisievert) as maximum threshold of exposure dose cumulative over a 5 year period. The compliance on this parameter is extremely critical as it can have serious implications when the exposure dose exceeds this limit. This research study has identified that the practice of timely submission of TLD badge with third party laboratories approved by AERB for estimation of exposure levels has been at moderate to significant levels as shown in Table 9. However practices related to monitoring of dosage level from the report published by third party lab, periodical QA test and managing incidents are found to be consistent with High level to very high level of compliance (Table 9).

More than 90 percent of the respondents have agreed that moderate level of compliance is practiced on the timely submission of TLD badges with third party external labs for testing (Fig. 6). Almost 95 percent of the respondents have confirmed that the review of actual dose levels from third party test reports happens meticulously and compliance is always above high levels (Fig. 6). Managing incidents due to excessive radiation by releasing the affected technicians on a long paid leave and performing QA tests for ensuring continued fitness of equipment are the practices followed with high to very high level of compliance as expressed by more than 90 percent of respondents (Fig. 6).

3.7 Top Management Commitment

The commitment from top management for putting together a high quality management system and best practices to comply with regulator guidelines for radiation protection has been gathered and summarized in Table 10. The distribution of responses has shown moderate to significant compliance on factors related to financial decisions and high to complete level of compliance on operations related decisions.

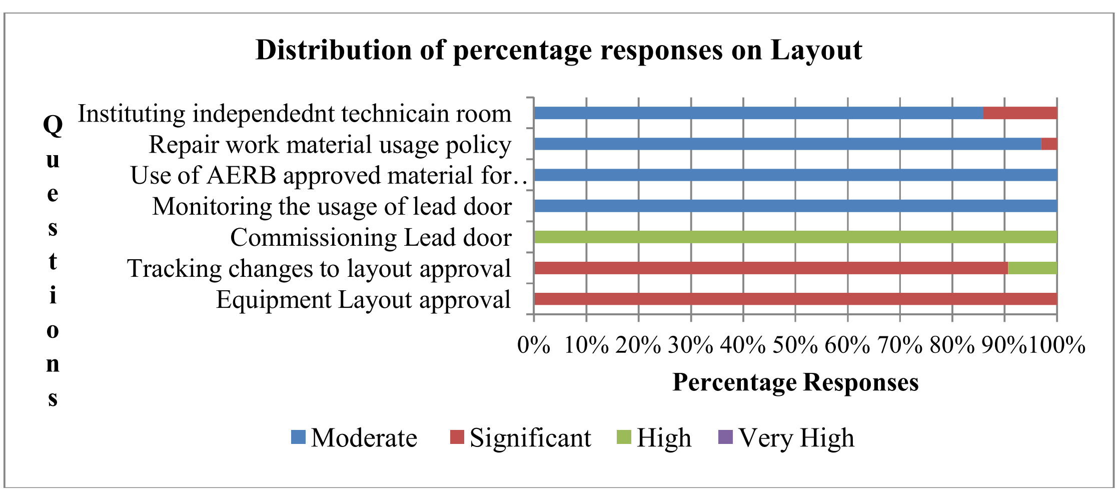


Fig. 2. Comparison of percentage responses for layout engineering

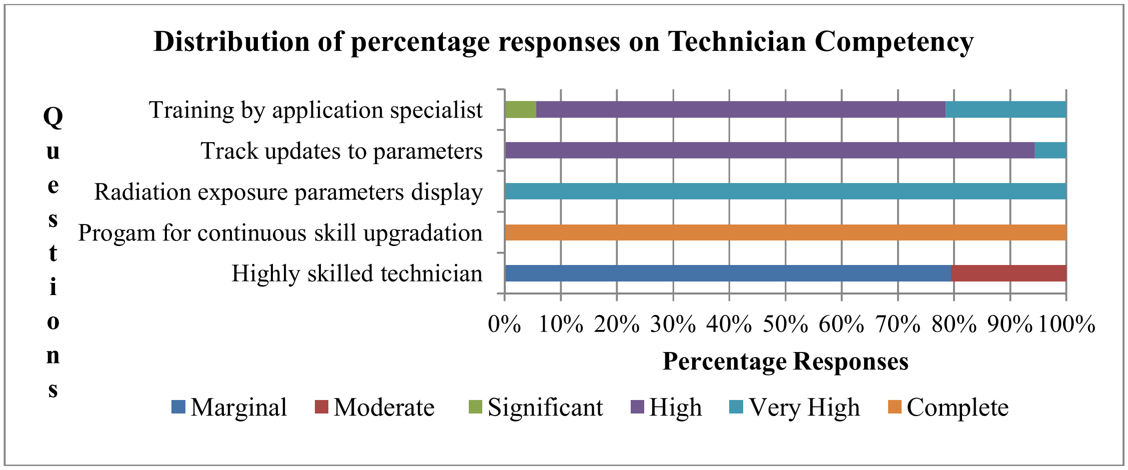


Fig. 3. Comparison of percentage responses for technician competency

Table 7. Distribution of responses on human safety

Sl. No	Questions	Responses			
		Significant (3)	High (4)	Very high (5)	Mode
1	Wearing TLD badge during scan		81	23	4
2	X-ray room door closure monitoring		98	9	4
3	Avoid crowding at X-ray room		104	3	4
4	Usage of Lead aprons for mobile X-ray	3	90	14	4
5	Equipment Quality Assurance Test at installation	6	80	21	4

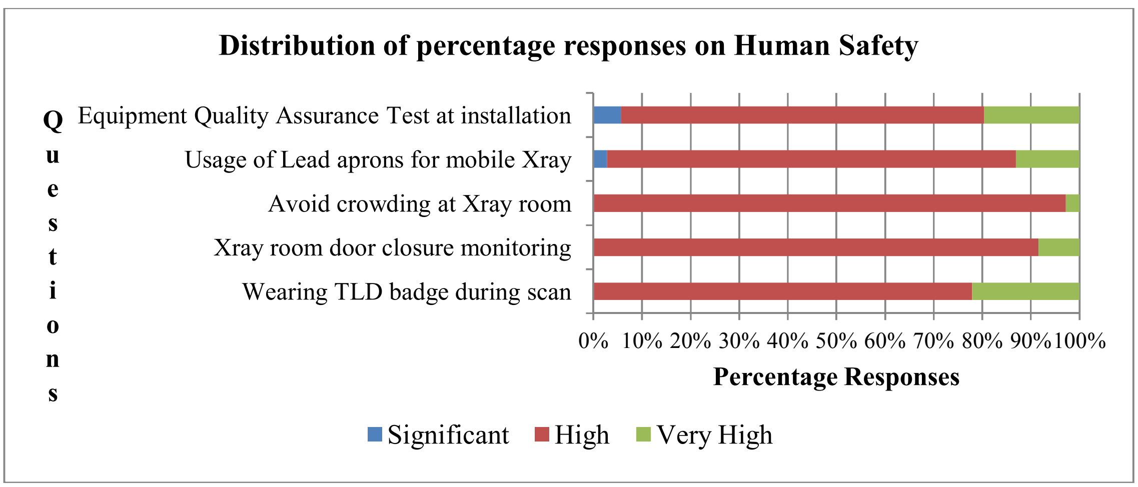


Fig. 4. Comparison of percentage responses for human safety

Appointing fulltime Radiation Safety Officer (RSO) who is considered to be the champion for leading regulatory compliance has not gained much priority as shown in the Fig. 7, where in close to 90 percent of responses revealed moderate compliance. Financial decisions on allocation of funds to test Aprons and engaging qualified service providers for annual maintenance have recorded only significant compliance as expressed by 100 percent of respondents. The compliance on Appointment of qualified service providers for QA test, decisions on outcome of QA test and stocking adequate aprons has registered Very High with 90 percent responses.

Table 8. Distribution of responses on operations know-how

Sl No	Questions	Responses					
		Marginal (1)	Moderate (2)	Significant (3)	High (4)	Very high (5)	Mode
1	Collimeter usage			5	92	10	4
2	Protecting abdomen while scanning pregnant woman			107			3
3	Storage of TLD badge when not in use			107			2
4	Signage's and radiation stickers	94	13				1
5	Usage of pediatric protocols		107				2
6	Maintenance of environmental conditions		97	10			2

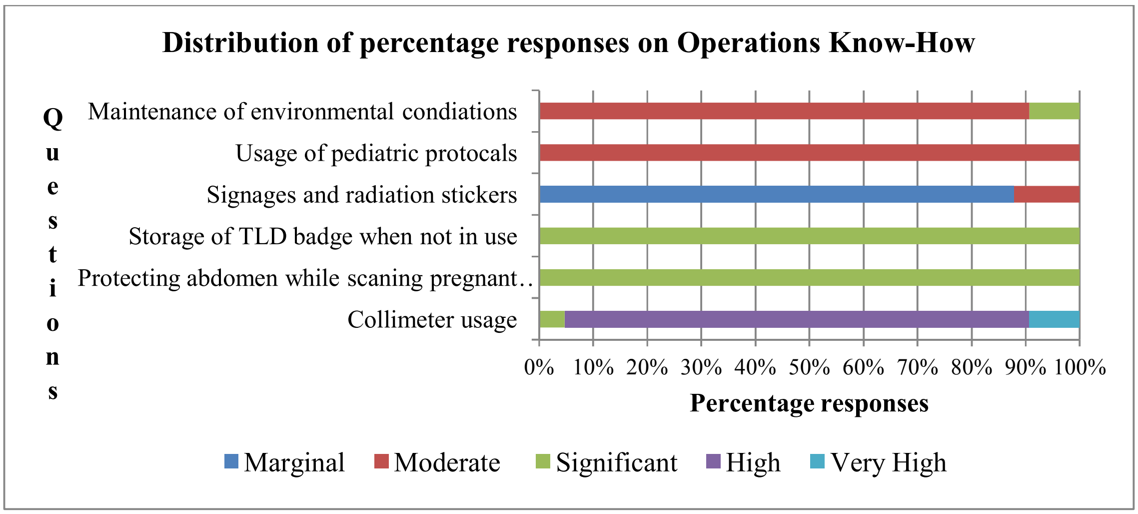


Fig. 5. Comparison of percentage responses for operations know-how

Table 9. Distribution of responses on monitoring radiation exposure

Sl No	Questions	Responses					
		Moderate (2)	Significant (3)	High (4)	Very high (5)	Complete (6)	Mode
1	Timely submission of TLD badge for analysis (Quarterly)	96	11				2
2	Monitoring the dosage levels of Technician		6	78	23		4
3	Performing periodical QA test (Every 2 Years)		3	81	23		4
4	Managing Exposure incidents			98	9		4
5	Evaluating AERB approved service providers				104	3	4

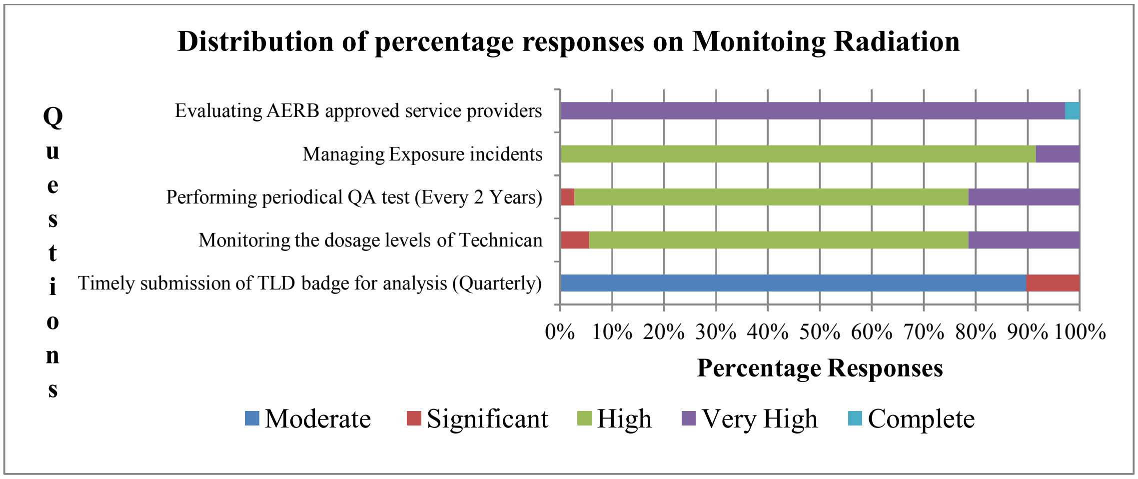


Fig. 6. Comparison of percentage responses for monitoring radiation exposure

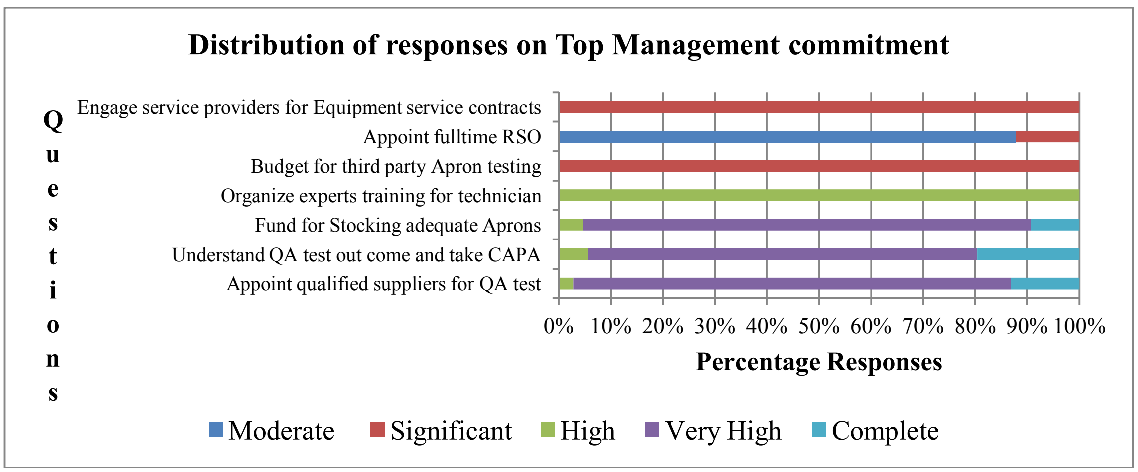


Fig. 7. Comparison of percentage responses for monitoring radiation exposure

Table 10. Distribution of responses on top management commitment

Sl No	Questions	Responses					
		Moderate (2)	Significant (3)	High (4)	Very high (5)	Complete (6)	Mode
1	Appoint qualified suppliers for QA test			3	90	14	4
2	Understand QA test out come and take CAPA			6	80	21	4
3	Fund for Stocking adequate Aprons			5	92	10	4
4	Organize experts training for technician			107			3
5	Budget for third party Apron testing		107				2
6	Appoint full time RSO	94	13				1
7	Engage service providers for Equipment service contracts		107				2

3.8 Testing of Hypothesis

The Diagnostic centers promote their identity in the market place with NABL (National Accreditation for Testing and Calibration Laboratories) accreditation. Hence, the researcher has formulated a null hypothesis and stated as "There will be no difference in compliance score between NABL and Non NABL Diagnostic chain of laboratories". The compliance score based on the responses has been grouped under NABL and Non-NABL (Table 11). The hypothesis was tested using Wilcoxon Rank Sum Test and the results are shown in Table 12.

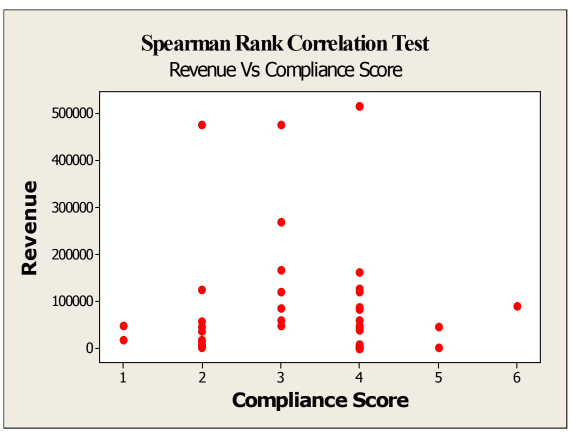
The '**P'** value estimated @ 95 percent confidence interval has shown .083 (Table 12), which is higher than the alpha value .05. Hence the null hypothesis is accepted. This test confirms that there is no significant difference in compliance between NABL and Non-NABL accredited diagnostic chain of laboratories. The test results prove that NABL certification did not influence the compliance on regulatory guidelines.

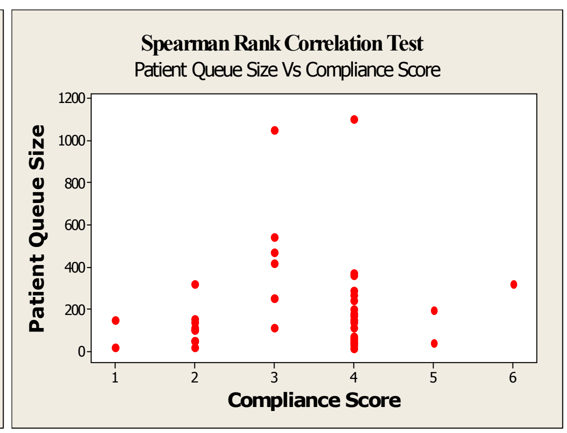
3.9 Relationship between Revenue and Compliance

The implementation of regulatory compliance needs substantial efforts and bears a tangible financial implication; it was decided to test whether the revenue earned by the chain of diagnostic centers will have an influence on the compliance. Spearman rank correlation test was performed with compliance and revenue data collated from the questionnaire (Table 11). The Spearman's rho value + .122 have shown a weak positive correlation and 'P' value + .429 brought out insignificant relationships (Fig. 8). Hence it was evident that the revenue did not impact regulatory compliance.

3.10 Relationship between Revenue and Patient Queue Size

It was decided to test whether the patient queue size will have an influence on the compliance. Spearman rank correlation test was performed with compliance and patient queue size based on the data collated from the questionnaire (Table 11). The Spearman's rho value - .093 have shown a weak negative correlation and 'P' value + .547 brought out insignificant relationships (Fig. 8). Hence it was evident that the patient queue size as well did not impact regulatory compliance.





Spearman Rho	-0.093182352	Spearman Rho	0.122121873
Degrees of freedom	42	Degrees of freedom	42
P- Value	0.54742778	P- Value	0.429698964

Fig. 8. Comparison of relationship between "compliance Vs revenue" and "compliance Vs patient queue size"

Table 11. Compliance score for NABL and non-NABL chain of diagnostic centers

Sl No	NABL compliance score	Non NABL compliance score	Overall compliance	Patient queue size	Revenue per day
1	3	3	3	545	120750
2	3	3	3	1050	270000
3	3	3	3	470	167000
4	3	3	3	250	49500
5	3	3	3	420	59500
6	4	3	4	240	84000
7	4	4	4	270	87000
8	4	4	4	200	60500
9	4	4	4	360	128000
10	4	4	4	290	121500
11	4	4	4	370	162000
12	5	4	5	195	47000
13	2	2	2	50	2500
14	2	2	2	100	5000
15	2	2	2	100	5000
16	2	2	2	50	9500
17	2	2	2	115	16250
18	6	5	6	320	89500
19	5	5	5	40	2000
20	4	4	4	50	2500
21	4	4	4	40	2000
22	4	4	4	60	3000
23	4	4	4	40	2000
24	4	4	4	70	3500
25	4	4	4	12	2000
26	4	4	4	180	9000
27	4	4	4	150	7500
28	3	3	3	250	86000
29	2	2	2	140	57000
30	1	1	1	150	47500
31	2	2	2	320	124500
32	2	2	2	100	47000
33	2	2	2	50	37500
34	4	4	4	110	43500
35	4	4	4	140	40000
36	4	4	4	150	47500
37	4	4	4	60	600
38	4	4	4	30	300
39	4	4	4	1100	515400
40	4	4	4	170	515000
41	3	3	3	110	476500
42	2	2	2	155	477500
43	1	1	1	20	18000
44	2	2	2	20	18000

Table 12. Wilcoxon rank sum test for test of hypothesis

Parameters	N	Mean	Std. deviation	Minimum	Maximum	Percentiles		
						25th	Median	75th
Compliance score NABL	44	3.30	1.112	1	6	2.00	4.00	4.00
Compliance score non-NABL	44	3.23	1.031	1	5	2.00	4.00	4.00

		N	Mean rank	Sum of ranks	Test statistics[a]	
Compliance score Non-NABL- Compliance score NABL	Negative Ranks	3[a]	2.00	6.00		
	Positive Ranks	0[b]	0.00	0.00	Z	-1.732[b]
	Ties	41[c]			Asymp. Sig. (2-tailed)	.083
	Total	44			a. Wilcoxon Signed Ranks Test	
	a. Compliance Score Non-NABL < Compliance Score NABL					
	b. Compliance Score Non-NABL > Compliance Score NABL				b. Based on positive ranks.	
	c. Compliance Score Non-NABL = Compliance Score NABL					

4. CONCLUSION

The Top Management involvement is essential in implementation of regulatory systems and it was evident from this study that high level of commitment seen in training technicians through experts, allocation of appropriate funds for stocking aprons and engagement of third party testing agency for conducting Quality Assurance tests. However, appointment of fulltime Radiation Safety Officer who is the change agent for driving regulatory system implementation and periodical testing of Aprons in external laboratories have not been implemented. The regulatory compliance covering facility approval by AERB, monitoring changes to facility approval and prominent display of facility approval were found to be the focus areas for implementation. Significant compliance is seen in layout engineering related areas focused on obtaining layout approval from AERB, tracking changes to layout approval and Lead door commissioning. Training the technician with the help of software application specialist from equipment manufacturer and enhancing knowledge levels on radiation exposure parameters were found to be the focus areas in competency enhancement, which are high compliant. There is no compromise on establishing high compliance to all the parameters that safe guard's technicians and patients safety, a parameter where in very high level of compliance is seen in all requirements stated under 'Human Safety". The Operations Know-How parameter compliance had TLD badge usage, monitoring X-ray room door closure, maneuvering collimeter and equipment QA tests as key focus areas for compliance. Monitoring of environmental temperature and humidity inside equipment room and prompt display of signage's / stickers were not effectively implemented. Hence this research study based on the objective test results has concluded that the regulatory parameters pertaining to protection of imaging equipments from excessive radiation has been well implemented in the chain of diagnostic laboratories. The scope of this research has been limited only with Tamil Nadu, India and further research can be explored with other states in India for assessing the extent of implementation of regulatory compliance towards protection of human safety from any excessive radiation exposure.

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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