

**GOVERNMENT OF INDIA
ATOMIC ENERGY
LOK SABHA**

STARRED QUESTION NO:231
ANSWERED ON:17.08.2011
SAFETY INSPECTIONS BY AERB
Abdulrahman Shri ;Kodikunnil Shri Suresh

Will the Minister of ATOMIC ENERGY be pleased to state:

- (a) whether the private clinics using MRI, Ultrasound, X-ray machines etc. are required to be registered with the Atomic Energy Regulatory Board (AERB);
- (b) if so, the details thereof;
- (c) the details of the agencies, institutions, etc. registered with the AERB and the benefits enjoyed by them;
- (d) whether such agencies/institutions are subjected to any review/inspections to ascertain adherence of the prescribed safety and other rules of AERB;
- (e) if so, the details of inspections carried out during each of the last three years and the current year, State-wise; and
- (f) the details of the agencies/institutions found to be violating the prescribed rules and safety norms and the action taken/proposed to be taken against them?

Answer

THE MINISTER OF STATE FOR PERSONNEL, PUBLIC GRIEVANCES & PENSIONS AND IN THE PRIME MINISTER'S OFFICE (SHRI V. NARAYANASAMY) :

(a) to (f) A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.231 BY SHRI ABDUL RAHMAN AND SHRI KODIKUNNIL SURESH REGARDING SAFETY INSPECTIONS BY AERB

(a) The medical X-ray equipment, being ionizing radiation generating units, of private clinics are also required to be Licensed/Registered with Atomic Energy Regulatory Board (AERB). MRI and Ultrasound units are not emitting ionizing radiation, so these units are not required to be registered with AERB.

(b) Licence/ Registration of medical diagnostic X-ray equipment is issued by AERB after verifying compliance requirements such as availability of Site and Layout Approval, Qualified Personnel, Type Approval of X-ray equipment and other safety specific requirement as per AERB Safety Code for Medical Diagnostic X-ray Equipment and Installations.

(c) The total number of equipment (Computer Tomography and Interventional Radiology) for which Licenses have been issued are 258 and the other X-Ray equipment Registered with AERB to date are 4479. AERB Licenses/registers equipment that conform to the safety requirements as prescribed by AERB. Since all parameters of radiation safety are assured, the patients, doctors, the radiation workers and all concerned with that diagnostic equipment are expected to be safe with respect to radiation exposure. Also, the AERB registration/licence of X-ray equipment is mandatory for National Accreditation Board for Hospitals and Healthcare (NABH), providers of accreditation.

(d) Medical X-Ray installations are subjected to regulatory review/ inspection by personnel authorized under Rules 30 and 31 of Atomic Energy (Radiation Protection) Rules, 2004. In view of the low hazard potential, such institutions are inspected on a random basis.

(e) The inspections carried out in the last three years are as follows:

State Year 2008 Year 2009 Year 2010 Year 2011

Tamil Nadu	-	-	-	10
Karnataka	-	12	-	21
Goa	-	-	2	1
Maharashtra	8	3	4	
Delhi	5	-	5	4
Rajasthan	-	6	-	5

Uttar Pradesh	1	-	4	-
Assam	-	-	-	4
West Bengal	-	-	-	1
Andhra Pradesh	-	-	-	15
Chandigarh	1	1	-	-
Meghalaya				3
Tripura				1
Madhya Pradesh	-	10	-	-
Haryana	-	-	1	-
Kerala (DRS)	7	9	22	59

(f) The licence(s)/registration(s) are issued to X-ray installations by the Competent Authority only after confirming that prescribed safety requirements are duly complied with by the institutions. The overall safety of X-ray installations depends largely on the built-in-design of X-ray machine and also the operational safety. For ensuring the design safety of X-ray machines, the Type approvals are issued by the Competent Authority, which ensures the built-in-safety features and safety interlocks of the machine. Hence the likelihood of radiological consequences in case of minor deviations of safety provisions are not so significant in case of X-ray installations in view of the safe design of X-ray machines. In case of any institution violating the prescribed safety rules or safety norms, there is provision that Competent Authority, based on the radiological consequences, may suspend/ modify/withdraw the licence / registration issued to that X-ray installation or seal X-ray installation(s) in accordance with Rule 10 and 31 of the Atomic Energy (Radiation Protection) Rules, 2004.

It is observed that in general, X-ray institutions/ agencies conform to the safety norms prescribed by the Competent Authority. However, non-compliances with regulatory requirements /safety discrepancies have been observed in some X- ray institutions but with no impact on overall radiological safety of the installation. The show cause notices have been issued to five such X-ray institutions (4 in Kerala and 1 in Karnataka) stating the non-compliances with safety norms. These institutions have already taken corrective actions and complied with the prescribed safety norms.