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Editorial

Need for dental radiology regulatory board (DRRB)

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1. Introduction

Oral Radiology is an essential part of modern Dentistry and brings very significant benefits for patients. Any use of ionizing radiation carries intrinsic risks. Diagnostic Radiology includes various modalities of imaging by using X-rays. However, unsafe use of x-ray radiation has health risks associated with it and hence it is required that proper care is exercised throughout the life cycle of the equipment i.e. from manufacture, supply, installation, use, maintenance, servicing and ultimately decommissioning.

Dental practice has its own way of radiation exposure. Though the exposure is minimal it is very important to reduce the radiation to avoid the accumulated dose to the dentist in their lifetime. Radiation is not only a source of energy, but it could also be a potential threat to human health, if not handled properly. To monitor and control such ionizing radiation in Dentistry, it becomes necessary to have regulatory body over it which lay down rules and regulations under proper legislation.

2. Currently Functioning Regulatory Boards

The International Commission of Radiation Protection (ICRP) is the international regulatory body, formed in 1928 to lay down norms for protection against radiation and recommend dose limits for radiation workers and general

public at the international level. The Indian regulatory board for protection against radiation is AERB, Atomic Energy Regulatory Board which was constituted on November 15, 1983. The mission of the boards is to ensure that the use of ionizing radiation and nuclear energy in India does not cause undue risk to health and surroundings.

The Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R-2004],¹ promulgated under the Atomic Energy Act, 1962, provides the legal framework for the safe handling of radiation generating equipment (in this context - X-ray equipment). As per Rule 3 of AE(RP) R-2004 it is mandatory for all the manufacturers/ Suppliers/Users of x-ray equipment, to obtain requisite 'Licence' from AERB for carrying out any of the above activities. It is mandatory to register all diagnostic radiation facilities in e-Licensing of Radiation Application (eLORA) system of AERB. From December 1st, 2013, it is compulsory for Dental practitioners and Dental institutions to register in eLORA and obtain a license to operate Dental X-ray units, panoramic machines, and cone beam computed tomography. It is also necessary for manufacturers of diagnostic X-ray machines to obtain a license for sale in India by AERB. Though registering to AERB is of utmost importance, most of the dentists are not aware of it.

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3. Need for Dental Radiology Regulatory Board (DRRB)

Regulation refers to “controlling human or societal behaviour by rules or restrictions.” Regulatory agencies deal in regulation or rule making and enforcing rules and regulations for the benefit of the public at large. Implementing such regulations in Dental Radiology through a separate regulatory body is a need of today. Lack of awareness among the Dental Practitioner about the use of radiation source, licensing of purchased radiation source and radiology equipment, radiation protection measures, approving layout design for radiology section made it mandatory to create a regulatory body that will function only for the benefit of Dental Radiations.

The purpose of these enhanced regulations is to “promote the mantra: every time a patient is exposed to Dental x-rays that it be . . . the right exam, for the right reason, at the right time.”

Currently working agencies for monitoring radiations in Medical and Dental field has to face many challenges like increasing workload, vast use of x ray source in different fields, lack of man power and qualified persons to carry out quality assurance of radiation sources and radiology equipment which initiate the thought of separate regulatory board for Dental Radiology Practise. At the same time manufacturing of Radiation equipment, many a times does not go Quality assurance which is a serious issue in today’s market. Approval of respective regulatory bodies are also being neglected by manufacturers. Thus, it becomes a need of having a functional regulatory body in the field of Dentistry.

Need of Dental Radiology Regulatory Board (DRRB) can be well understood under following heads.

4. Objectives of Dental Radiology Regulatory Board (DRRB)

1. The fundamental objective of DRRB should be to ensure that the use of ionizing radiation in Dental Practice does not cause undue risk to the health of people and the environment.
2. Develop safety policies in Dental Radiation and its safety areas for facilities under its purview.
3. Develop Safety Codes, Guides and Standards for siting, design, construction, commissioning, operation and decommissioning of different types of ionizing and non-ionizing radiation facilities use in Dentistry.
4. Grant consents for siting, construction, commissioning, operation and decommissioning, after an appropriate safety review and assessment, for establishment of radiation facilities in Dental setups.
5. Ensure compliance with the regulatory requirements prescribed by DRRB during all stages of consenting through a system of review and assessment, regulatory

inspection and enforcement.

6. Prescribe the acceptance limits of radiation exposure in Dental radiology practice to occupational workers and members of the public.
7. Review the emergency preparedness plans for radiation facilities used in Dentistry.
8. Review the training program, qualifications and licensing policies for personnel of radiation facilities in Dental Radiology and prescribe the syllabi for training of personnel in safety aspects at all levels.
9. Take such steps as necessary to keep the public informed on major issues of Dental radiological safety significance.
10. Maintain liaison with statutory bodies in the country (like Atomic Energy Regulatory Board, Bhabha Atomic Research Centres), as well as abroad (like International commission of Radiation Protection) regarding safety matters.
11. Promote Dental Radiology research and development efforts in the areas of safety.
12. Review the Dental diagnostic Radiations facilities under its purview.
13. Promote awareness among the Dental practitioners about safety matters, use and controlling of radiations

The awareness and practice of radiation protection measures is found to be unsatisfactory. Though some dentists have adopted newer and better radiographic techniques, attitude towards minimizing radiation hazards is disappointing. All the dentists should attend educational programs on basic imaging in dentistry and radiation protection on a regular basis. Certification of X-ray machines and regular calibration of the machine is mandatory. Every dentist should practice Dental radiology in an ethical manner by following the ALARA principle and making it safe for the patients and themselves.

The Dental Regulatory Authority can be empowered and must undertake the following functions:

1. To issue regulations (or to prepare regulations for legislative adoption) governing notification, authorization and exemption of practices and radiation sources and establishing radiation protection and safety requirements while practising Dental Radiology.
2. To define the exposures that are excluded from regulatory requirements on the basis of their being unamenable to regulatory control.
3. To issue authorizations and grant exemptions concerning the possession and use of radiation sources.
4. To define in the regulations and authorizations the detailed obligations, including financial conditions, to be placed on those who possess radiation sources.
5. To conduct inspections in Dental institutions, hospitals and clinics to assess radiation safety conditions and

compliance with applicable regulations and other requirements specified in an authorization.

6. To take such action as is necessary to enforce the requirements in any regulations and authorization and to protect the health and safety of workers and the public.
7. To assist in emergency response..
8. To initiate, recommend, or provide support on intervention, as appropriate.
9. To advice other governmental authorities and organizations on matters within the competence of the Regulatory Authority.
10. To promote or carry out research on radiation safety issues of regulatory concern.
11. To maintain contact for information exchange and cooperation with regulatory bodies of other countries and relevant international organizations.
12. To establish appropriate mechanisms to inform the public about the regulatory process and the radiation safety aspects of regulated practices.

5. Basic Elements of a Dental Regulatory Programme

Radiation safety of sources established and maintained through a Dental regulatory programme should consist of:

1. Regulations which set forth requirements and standards for protection and safety and related administrative requirements.
2. A system of notification and authorization (registration or licensing) for control over possession and use of radiation sources.
3. Provisions for establishing exclusions and granting exemptions from regulatory requirements..
4. Compliance monitoring, including inspection, to assess the status of safety and compliance with regulatory requirements.
5. Enforcement to compel compliance with regulatory requirements.
6. Investigation of accidents and management of emergencies and
7. Dissemination of information on protection and safety.

Establishing clear guidelines for obtaining licence of X ray source, registration of Dental units, declaring employees who will handle X ray source, obtaining Radiation safety Officers approvals, installation and declaration of radiology instruments, preparing and designing layout and approving it, carrying out Quality assurance programme, renewal of licences, decommissioning of radiological equipments will be the primary objectives of Dental Radiology Regulatory Board.

6. Principles of Dental Radiology Regulatory Board (DRRB)

The desirable attributes and practices of Dental Radiology Regulatory Board for Radiation products should have following principles on which regulatory systems may be established

Legality: Dental Radiology Regulation should have a sound legal basis and should be consistent with existing legislation, including national & international norms or agreements.

Impartiality: Dental Radiology Regulation and regulatory decisions should be impartial in order to be fair and to avoid conflicts of interest, unfounded bias or improper influence from stakeholders.

Consistency: Regulations in Dental Radiology should be clear and predictable; both the regulator and the regulated party should understand the behaviour and the conduct that are expected and the consequences of noncompliance.

Proportionality: Regulations and regulatory decisions should be proportional to the risk and should not exceed what is necessary to achieve the objectives in Dental Radiology.

Flexibility: Regulations should not be prescriptive; they should allow flexibility in responding to a changing regulated environment and different or unforeseen circumstances.

Effectiveness: Dental Radiology Regulations should produce the intended result.

Efficiency: Dental Radiology Regulations should achieve their goals within the required time, effort and cost.

Clarity: Dental Radiology Regulations should be accessible to, and understood by, the users.

Transparency: Dental Radiology Regulatory systems should be transparent; requirements and decisions should be made known to affected parties and, where appropriate, to the public in general.

7. Regulatory Goals of DRRB for Dental X Ray Equipments

Regulation of use of X-ray equipments in Dentistry shares two important goals. The first objective of regulation is to protect the public health and safety by preventing the marketing of unsafe or ineffective products. The second goal of regulation is to promote the availability of safe and effective products that will enhance the public health and safety. Regulation of Dental products that emit ionizing radiation is no different than regulation of any other form of therapeutic or diagnostic products in these two respects. Thus Intraoral X-ray Machines, (Full body 100 mA) Extraoral X-ray Machines, Panoramic machines, Cone Beam Computed Tomography machines, Portable X-ray source or equipments used in Dental radiology should have valid approval of such Regulatory bodies which undergoes

Quality assurance tests.

8. Framework of DRRB

Development of safety documents, safety review and issue of license, authorization to Dental radiation facilities, verify compliance with stipulated requirements by radiation facilities, regulatory inspections, safety research, licensing of key operating personnel, review of emergency preparedness and public information are mainstay functions and responsibilities of Dental Radiology Regulatory Board (DRRB).

It is essential that the responsibilities of the Dental Radiology Regulatory Board (DRRB) are kept completely distinct from those of any other party so that the regulators can preserve their independence of judgment and decision as safety authorities. For this purpose, there should be clear separation of functions and responsibilities of the Dental Regulatory Authority from those of other government departments and agencies having responsibility for development and promotion of regulated practices. There should also be a clear separation or independence of the Dental Regulatory Board from those subject to regulation, e.g., registrants, licensees and manufacturers of radiation sources. In addition, the Regulatory Authority should avoid engaging in activities which could compromise or appear to compromise that separation, e.g. providing consultant services.

9. Challenges & Future Perspectives of DRRB

Establishing a new regulatory body along with already existing boards can face various challenges. Formation of legislature, constructing a specific framework and working pattern will be the primary outlook challenge for DRRB. Critic for the need of such bodies will always make a challenge stronger. Thus, future of DRRB will always depends on the established framework. In this specific field of Dental Radiology, if monitoring and controlling of Ionizing radiation is made under exuberant board, it will always be beneficial for development of safe environment for every individual.

10. Conclusion

Radiation has become a part of modern living, reaching every segment of our society. All individuals are exposed

to ionizing radiation, both from natural and man-made radiation sources. Although the radiological doses used by dentists are low individually, patients are often exposed to many repeat Dental Radiographic examinations. The ‘routine’ use of Dental radiography, such as screening of all patients using Dental panoramic radiography or a random decision to take a Dental radiograph, will inevitably lead to unnecessary patient exposure. The use of Radiographic Referral Criteria has now become a legal requirement for all practitioners. All exposures to x-rays should be clinically justified and each exposure should be expected to give the patient a positive net benefit.

Though exposure to radiation in dentistry is minimal, it is very important to follow the guidelines to minimize the radiation exposure. Following the safety guidelines while constructing the Dental Radiological unit and monitoring the individual exposure and quality of instruments is very useful in radiation protection. Knowledge on the type of radiologic equipment and the calibration of the machine during purchase and later should be made mandatory. The simple steps during the establishment of the radiological units and compliance for the guidelines will help the individual for dose reduction in Dental practice. Regulatory bodies which functions with policy development, resource stewardship, legal compliance, partner engagement, continuous improvement and oversight can be the only solution for such challenges of radiation safety in Dental Radiology.

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