ROLE OF BARC IN QUALITY ASSURANCE AND SAFETY IN MEDICAL APPLICATIONS OF IONIZING RADIATION

B. C. Bhatt

Introduction

Ionising radiation is being used extensively in human healthcare programmes. The medical application of ionising radiation is unique in that patients are intentionally exposed to it for diagnosis and therapy purposes. Radiation therapy ranks, along with surgery and chemotherapy, as the most powerful and effective modality for the treatment of cancer. Recent reports suggest that more than 60% of cancer cases are amenable to radiation treatments. In addition, nuclear medicine has become an established practice during the last three decades and is increasingly being employed for the detection and treatment of diseases and evaluation of physiological and pathological behaviours, not detected by any other diagnostic procedures. Over 90% of total radiation treatment is conducted by teletherapy/ brachytherapy, with radiopharmaceuticals being used in only 7% of treatments. Current estimates put the worldwide annual number of diagnostic exposures at 2500 million and therapeutic exposures at 5.5 million. Some 70% of diagnostic exposures are due to medical X-rays, 21% due to dental X-rays and remaining 1% due to nuclear medicine techniques (UNSCEAR, 1993)[1].

While ionising radiations play a significant and indispensable role in diagnosis and treatment of cancer, it must be borne in mind that it may be harmful to the radiation workers and the public, if used indiscriminately and without due caution. Concern for radiation protection and regulations is growing significantly not only due to the rapid increase in the use of ionising radiation but also because of better understanding of the risk and benefits attributable to it. It is therefore necessary to ensure the safety of radiation workers, patients undergoing diagnosis and treatment, the public and the environment so that maximum benefit is derived from the safe use of radiation

with minimum acceptable risk. With the publication of ICRP 60 (1990)[2] and International Basic Safety Standards[3], there have been all round efforts to appropriately revise the radiation protection criteria and adopt recommendations contained in these reports.

Radiation Therapy Facilities in India

Radiation therapy plays a vital role in cure and alleviation of sufferings of cancer patients. In India, it is estimated that over 1 million cancer cases are detected every year and a majority of them require radiotherapy at one time or other during their course of the treatment. Based on a rate of nearly one machine per every 800 - 1000 new cases of cancer, the number of treatment units available at present is only about one fourth of the requirement.

To accommodate the large workload, machines are often operated in two or three shifts. A break-up of radiotherapy facilities in India is given in Table 1. There are about 289 teletherapy units spread over 177 radiotherapy centres. About 113 of these centres have brachytherapy facilities, either manual, remote or both. Besides, there are about 140 nuclear medicine centres in the country, of which 25 centres have facilities for treatment of cancer of thyroid. Fig. 1 shows the annual growth pattern for radiation therapy facilities in India during the period 1980 - 2000. Photographs of typical models of telecobalt, medical linear accelerator, remote afterloading brachytherapy units, dosimeters routinely used for beam dosimetry, surveymeters and personnel monitoring TLD badges are given at the end of this arcitle.

With the availability of newer modalities of treatment in radiotherapy, such as medical linear accelerators with MLC, micro-MLC and dynamic MLC facilities, X-knife and Gamma Knife units, integrated remote afterloading brachytherapy, Sim-CT and CT-Sim systems for visualisation and localisation, and computerised treatment planning systems with 3-D facilities, radiation oncology scenario in the country is poised for a major leap forward and is tending towards technology oriented treatment delivery.

Quality Assurance (QA) of Radiotherapy Equipment

Quality assurance in radiotherapy embodies in itself all those procedures that ensure consistency and accuracy in dose delivery as prescribed by radiation oncologist, and correct fulfilment of dose

Table 1: Break-up of Radiation Therapy Facilities in India

Radiotherapy Centres in India	177
Radionuclide Therapy Units	252
Linear Accelerators	37
Remote Afterloading LDR/MDR Units	37
Remote Afterloading HDR Units	42
Manual Afterloading Intracavitary Kits	76
Manual Afterloading Interstitial Kits	27
Radiotherapy Simulators	40
Treatment Planning Systems	80
Nuclear Medicine Centres	140
Nuclear Medicine Therapy Centres	25

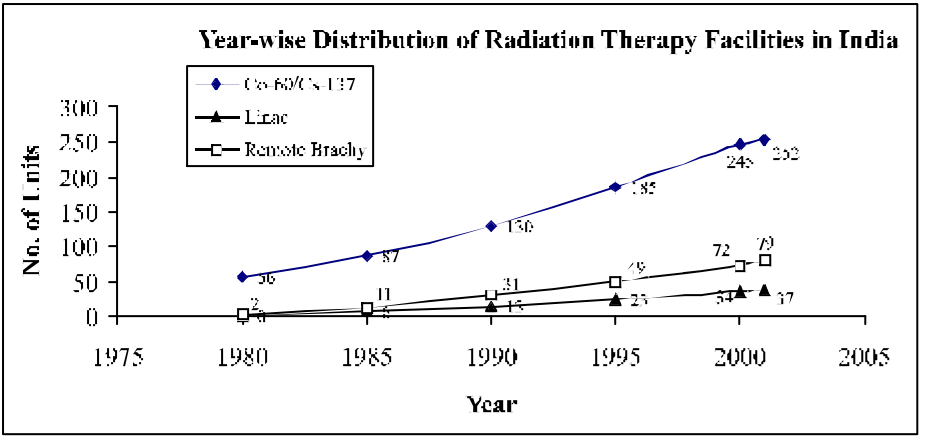


Fig. 1 : Year-wise distribution of growth of radiation therapy facilities in India.

prescription with regard to dose to the target volume, together with minimal dose to normal tissue, minimal exposure to occupational workers and adequate patient monitoring aimed at determining the end result of the treatment[10-13]. Thus, QA is an essential component of safe practice. Clinical studies and retrospective data analysis have proved that the dose delivered to tumour must be within (5% of the prescribed dose to achieve meaningful and acceptable tumour control.

This requires that physical dosimetry must be accurate to within (3% or better. Realisation of these objectives demand development and implementation of functional quality assurance programme for equipment, dosimetry, treatment planning and dose delivery technique. RP&AD has developed QA protocols for periodic quality assurance of radiotherapy equipment. A summary of these protocols has been presented in Table 2.

Table 2 : Quality Assurance Parameters for Radiotherapy Equipment

Telecobalt Units	Medical Linear Accelerators	Remote Afterloading Units
Functionality of electrical switches, interlocks, displays, etc.	Functionality of electrical switches, interlocks, displays, anti-collision systems, controls, etc.	Functionality of electrical switches, interlocks displays, controls, etc.
Accuracy of ODI and alignment of Lasers	Accuracy of ODI and alignment of Lasers	Reproducibility of source position
Accuracy of scales (linear/ angular)	Accuracy of scales (linear/angular)	Accuracy of source positioning
Symmetry and orthogonality of collimating jaws	Symmetry and orthogonality of collimating jaws	Accuracy of source sequence/source stepping
Constancy of isocentre	Constancy of isocentre	Integrity of applicators
Coincidence of optical and radiation field	Coincidence of optical and radiation field	Source strength verification
Beam flatness and symmetry	Beam flatness and symmetry	Accuracy of data transfer
Verification of radiation output	Constancy of radiation output (all energies)	Timer accuracy and linearity
Constancy of dosimetry parameters	Constancy of dosimetry parameters (all energies)	Leakage radiation from source safe
Surface dose, dmax and penumbra width	Surface dose, dmax and penumbra width	Radiation protection survey
Radiation Leakage through head and collimators	Radiation Leakage through head and collimators	_____
Radiation protection survey	Constancy of beam quality	_____
_____	Radiation protection survey	_____

Quality audit is another important tool for the evaluation of the adequacy of the radiotherapy treatments being delivered. Towards this end, Radiation Standards Section of RSSD, BARC conducts IAEA/ WHO Postal Dose Intercomparison programmes for verification of accuracy of output calibration of teletherapy machines using thermoluminescent detectors (TLDs). Results of postal dose intercomparison are given in Table 3. The basic aim of postal dose intercomparison service is to ultimately ensure that the doses delivered to the treatment volume do not show variations more than ±5%. It is also internationally accepted that dose distribution across the clinical target volume (CTV) better than ±5% leads to acceptable treatment outcome for cancer patients.

Table 3 : Results of TLD Dose Intercomparison*

	1997		1998		1999			2000
	First Cycle	Second Cycle	First Cycle	Second Cycle	First Cycle	Second Cycle	Third Cycle	—
No. of Machines covered	40	30	39	35	28	21	62	77
Results within 5%	32	21	31	25	21	13	57	64
Results within 5-10%	8	5	5	8	5	5	5	7
Results above 10%	0	4	3	2	2	3	0	6

* Data provided by Radiation Standards Section, RSSD, BARC

Brachytherapy Source Standardization Programme

National regulatory authority mandates that all radiation sources used for therapeutic applications should have calibration traceable to National Standards laboratory, as it is the practice internationally. The activities of the Radiation Standards Laboratory (RSL), RSSD and MPSS, RP&AD for implementation of these requirements are shown in

Fig. 2. While RSL is responsible for providing calibration service and offering traceable calibration to all users, MPSS conducts on-site quality assurance/quality audit in all the medical institutions in the country.

The RSL and MPSS, BARC maintain separate reference well ionization chambers, both traceably calibrated against the Primary Standard of Air Kerma Strength (AKS), but serving different objectives. While RSL takes the responsibility for calibrating hospital chambers, one of the responsibilities of MPSS is to audit these centres for regulatory compliance with regard to in-house QA that includes source calibration check. In this capacity, MPSS staff regularly visits medical institutions for external audit and in case of significant deviation in source calibration (compared to regulatory or recommendatory requirement of tolerance) advises the hospital to approach the RSL for recalibration.

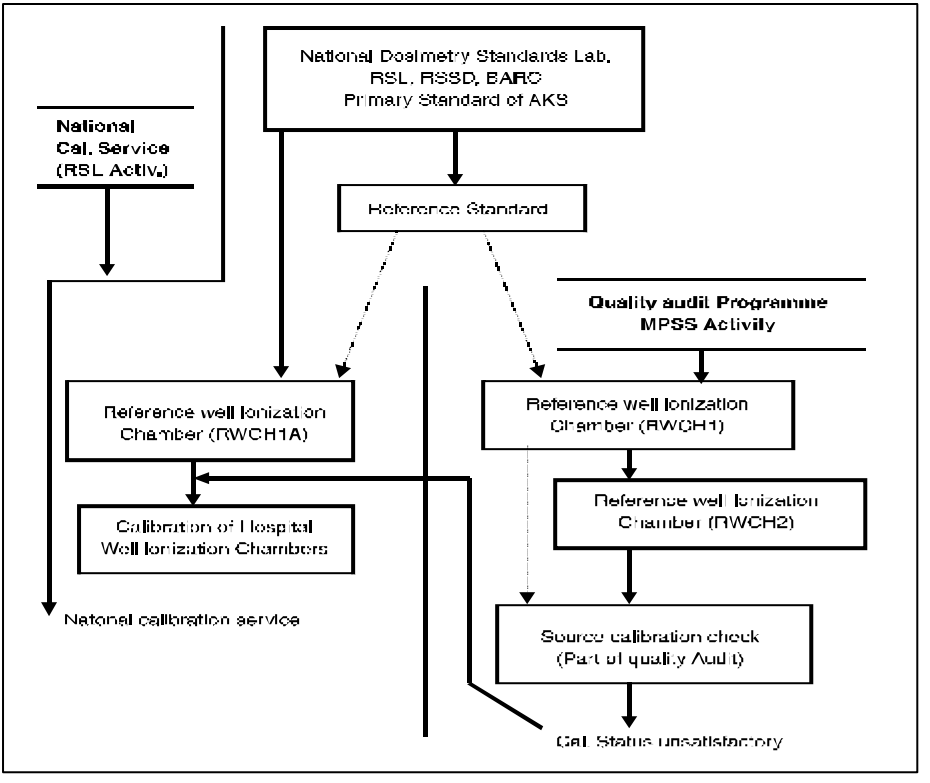


Fig. 2 : Activities of RSL, RSSD and MPSS, RPAD in the National Brachytherapy Source Standardization and Traceability Programme

Legislation

The primary legislation for the regulation of radiation protection in the use of ionizing radiation and radiation sources, in India, is the Atomic Energy Act, 1962[4]. The Act and the secondary legislation, viz., Radiation Protection Rules, 1971 (RPR-1971)[5] were promulgated by the Parliament. The Act empowers the Government of India to exercise control over production and the use of atomic energy. Special provisions to safety, under Section 17 and powers to make rules under Section 30 of the Act envisage control over premises where radioactive substances are handled or radiation generating equipment are operated. The Act lays stress on safety while working with radiation. It deals with control over the possession, use, sale, export and import, transport and disposal of radioactive materials, and cognizance of offences. Accordingly, RPR-1971 was promulgated and surveillance procedures for industrial radiography, safe transport of radioactive materials and medical application of radiation etc. were formulated and relevant notifications were issued by the Competent Authority. Acts, rules and other surveillance procedures[6-8] related to radiation protection in medical applications are listed in Table 4.

Table 4 : Acts, Rules and Surveillance Procedures Related to Radiation Protection in Medicine in India

- Atomic Energy Act, 1962[4]
- Radiation Protection Rules, 1971[5]
- Constitution of Atomic Energy Regulatory Board, 1983
- Safe Disposal of Radioactive Waste Rules, 1987[6]
- Radiation Surveillance Procedures for Safe Transport of Radioactive Materials, 1987[7]
- Radiation Surveillance Procedures for Medical Applications of Radiation, 1989[8]

Atomic Energy Regulatory Board (AERB)

Atomic Energy Regulatory Board (AERB) was constituted in 1983 under Section 27 of Atomic Energy Act, 1962. It is an apex body regulating the use of ionizing radiation in the country. The Board is fully empowered to lay down standards and frame rules and regulations. The Chairman, AERB is the competent authority for

enforcement of radiation protection. The mission of the Board is to ensure that the use of ionizing radiation and nuclear energy does not cause undue risk to health and environment. The Board covers the safety aspects of all areas of nuclear fuel cycle and use of radiation in medicine, industry, agriculture and research as well as in the transport of radioactive materials. The Board is supported by Health, Safety & Environment Group of BARC for carrying out its executive functions on a day-to-day basis. The Board is also assisted by several advisory committees and task groups.

The Atomic Energy Regulatory Board has powers to lay down safety standards and frame rules and regulations therein with regard to the regulatory and safety requirements envisaged under the Atomic Energy Act, 1962. The Board's functions include development of safety codes, guides, and standards. It also issues necessary guidelines for the site, design, construction, commissioning, operation and decommissioning of radiation installations. Review of operating procedures, and specifying limits and conditions for radiation work are also integral part of the Board's function. The Board, with active participation of experts, has developed and issued a large number of appropriate codes, guides, standards and manuals, some of which are currently under revision.

Health, Safety and Environment Group (HS&EG)

Department of Atomic Energy, Government of India deals with several aspects of atomic energy, ionizing radiation and radiation sources. Organizational structure for implementation of radiation safety and regulations in India is outlined in Fig. 3 below.

Health, Safety and Environment (HS&E) Group, Bhabha Atomic

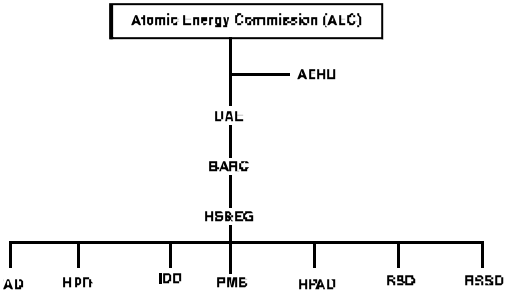


Fig. 3 : Organizational Structure for Implementation of Radiation Safety and Regulations in India

Research Centre (BARC), Mumbai, acts as the primary agency for implementing radiation protection and safety. Safety programmes of the group include Radiation Emergency Preparedness. BARC is actively considering to get recognition as regional center for WHO Radiation Emergency Medical Preparedness and Assistance Network (WHO-REMPAN). This will be a specialized facility for medical management of radiation injuries to exposed persons. HS&E Group provides the necessary advice and training in the application of radioisotopes and radiation. Radiological Physics and Advisory Division (RP&AD) is providing advisory services to AERB in implementation of rules and regulations framed under Atomic Energy Act, 1962 and RPR, 1971. RP&AD evaluates and approves the siting, planning and layout of the radiation installations from radiation safety standpoint, conducts and evaluates the pre-commissioning and post-commissioning radiation protection surveys of the facilities to monitor the safety status of the installation, sends appropriate recommendations to AERB for according commissioning permission to the facility and conducts a number of training programmes tailored to meet radiation protection needs for various types of facilities. The competent authority approves the nomination of RSO on recommendations of RP&AD. RP&AD also conducts technical evaluation of diagnostic and therapy equipment for type approval purposes, advises and helps users in framing and instituting a suitable quality assurance programme and acceptance testing procedures for the equipment.

Radiation Safety Systems Division (RSSD), under this Group, provides traceable calibration for therapy level and protection level instruments in the application of radiation in medicine, industry, research and agriculture and also conducts postal dose intercomparison programme for teletherapy machines. RP&AD and Personnel Monitoring Section (PMS) provide personnel monitoring service to occupational radiation workers. RP&AD also maintains lifetime dose records of these workers.

Type Approval (TA) of Radiation Generating Equipment

In India, it is a mandatory requirement that only type approved radiation-generating equipment shall be used for all applications. AERB issues necessary type approval certificate on receipt of

technical evaluation report and recommendations from RPAD. Towards this end, RPAD has evolved and tested appropriate protocols. These protocols/procedures are in conformity with similar international protocols (IEC, 1989)[9].

Table 5 : Status of Type Approved Radiation Generating Equipment in India

1. TELETHERAPY EQUIPMENT		
Telecobalt Units	**Medical Linear Accelerators (Linacs)**	
Theratron 780	Philips	SL 75 - 5
Theratron 780 C		SL 20
Theratron 780 E	Siemens	Mevatron MD
Theratron Phoenix		Mevatron KDS - 2
Theratron 1000E		Primus
Theratron Elite 80	Varian	Clinac 6/100
Theratron Elite 100		Clinac 1800
Alcyon		Clinac 2100 C
Cirus		Clinac 2300 C/D
ATC - 9	Elekta	SL 75 - 5
		SLi
		SLi Plus
		Precise
Total Type-Approved Cobalt Units: 10	**Total Type-Approved Linacs: 13**	
2. REMOTE AFTERLOADING BRACHYTHERAPY UNITS		
Nucletron	Selectron LDR/MDR (137Cs)	
	Selectron HDR (60Co)	
	MicroSelectron LDR/MDR (192Ir wire)	
	MicroSelectron HDR (192Ir single source)	
	MicroSelectron HDR-TCS (192Ir single source)	
Isotopen Technique	Gammamed 12i (192Ir single source)	
	Gammamed Plus (192Ir single source)	
Varian	VariSource (192Ir single source)	
	Total Type-Approved Afterloading Units: 8	

In case a new model of an equipment is to be installed, the manufacturer/vendor is required to submit the detailed specifications of the unit, dosimetry and radiation protection data, as measured by a qualified expert at the factory site, and a copy of the type approval certificate issued to the manufacturer by the regulatory authority of the country of origin of the equipment. Based on the evaluation of data furnished by the manufacturer/vendor permission is granted to install one such unit and demonstrate its compliance with the standard specifications. Pre-commissioning acceptance tests, on the performance of the equipment, are then carried out by RP&AD to ensure its compliance with the specifications. Status of type approved medical linear accelerators, telecobalt units and remote afterloading brachytherapy units is shown in Table 5. It includes 10 models of cobalt-60 units, 13 models of medical linear accelerators and 8 models of remote afterloading brachytherapy units.

502 models of diagnostic X-ray units have also been type-tested and approved by RP&AD for their safe use in diagnostic procedures. Fig. 4 depicts pictorially the type-approved status of various models of diagnostic X-ray units.

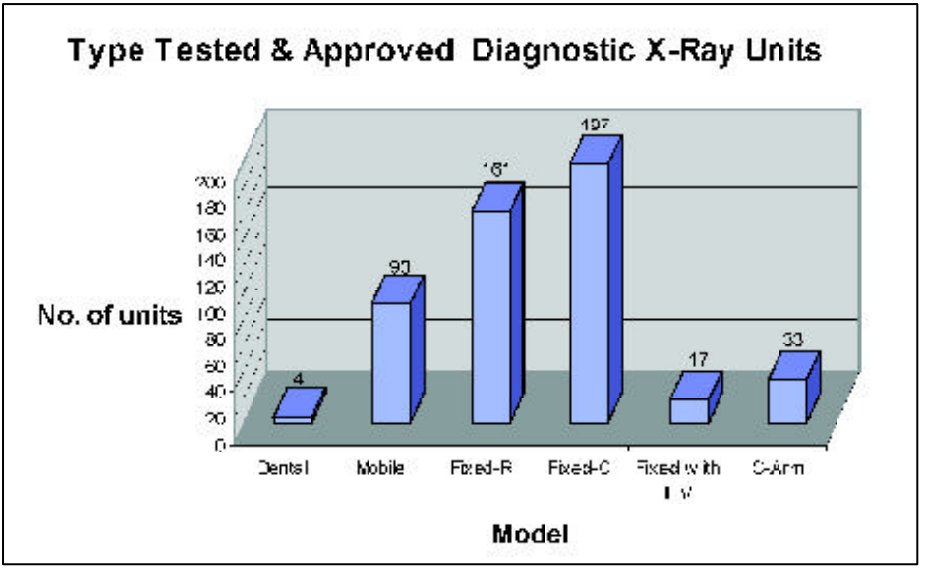


Fig. 4 : Type approved status of various models of diagnostic X-ray units.

Personnel Monitoring Service for Occupational Workers

Personnel or individual monitoring service is an integral part of radiation protection and safety programme. The purpose of personnel monitoring is to obtain an estimate of effective dose due to the occupational exposure of radiation workers. All occupational workers of radiotherapy centres in the country are covered by personnel monitoring services conducted by BARC and M/s Renentech Laboratories Pvt. Ltd., Mumbai, an Accredited Laboratory. Average annual effective dose of occupational workers engaged in various medical practices in India is listed in Table 6. From this table it is observed that dose received by the occupational workers are well within the stipulated limits.

Table 6: Average Effective Dose (mSv) of Medical Occupational Workers in India

Year	Diagnostic Radiology	Radiotherapy	Nuclear Medicine
1990	0.25	0.82	0.62
1991	0.24	0.74	0.74
1992	0.3	0.65	0.73
1993	0.23	0.62	0.62
1994	0.24	0.69	0.49
1995	0.24	0.71	0.73
1996	0.19	0.59	0.57
1997	0.22	0.68	0.7
1998	0.24	0.67	0.59
1999	0.19	0.38	0.47
2000	0.25	0.55	0.54

Radiation Safety Related Training Programmes

A comprehensive radiation protection and safety training programme will enable the staff to conduct their work in accordance with the requirements of Basic Safety Standards. Periodic refresher courses/ retraining programmes are necessary to update the knowledge of the personnel.

Table 7: Radiation Safety Related Training Programmes for Medical Applications of Radioisotopes up to August 2001

S. No.	Programme	Duration	No. of Courses	Persons trained
1	Diploma in Radiological Physics	1 year	39	598
2	Radiation Safety for Radiotherapy Technicians	8 days	23	368
3	Radiation Safety in Servicing of Radiotherapy Equipment	7 days	5	84
4	Radiation Safety in Research Applications of Radioisotopes	6 days	22	493
5	Quality Assurance in Diagnostic Radiology	4 days	2	40
6	Radiological Physics Training to Anna University Students	10 days	19	191
7	Diploma in Radiation Medicine (DRM)*	1 year	15 candidates per year since 1963	
8	Diploma in Medical Radioisotope Technology (DMRIT)*	1 year	15 candidates per year since 1963	

*Conducted by Radiation Medicine Centre, BARC, Parel, Mumbai. All the others courses are conducted by Radiological Physics & Advisory Division, BARC

One of the major contributions of RP&AD has been in conducting radiation safety related training programmes in the field of medicine, industry, agriculture and research. This has provided trained manpower to the country in the field of radiation safety. A Variety of training courses in the field of radiation medicine, as listed in Table 7, of different duration are organised each year. One of the most popular courses is the One-Year Diploma in Radiological Physics (Dip. R. P.). A post-graduate diploma is awarded by the University of Mumbai to the successful candidates. The course is aimed at providing qualified medical physicists and radiation safety officers to hospitals and industries using radiation sources*. As per the present regulation, availability of a qualified radiation safety officer is a precondition for obtaining authorization for procurement and use of radiation source. About 598 physicists including 21 from abroad have been trained since

1962. About 50% of these are employed in cancer hospitals in India and abroad and about 20% in industries, and the rest in other disciplines.

Conclusions

Radiation safety practices, if followed as per the recommended standards, could ensure radiation protection and safety for radiation workers and the general public. Quality assurance with respect to equipment/installation and work practice plays a key role in ensuring protection and safety. Availability of trained manpower is very important in any radiation safety programme. A well established radiation safety set up and administrative control are essential to fulfill the radiation protection requirements in any practice/application to derive optimum benefit from use of radiation sources.

Acknowledgements

The author wishes to thank Shri K.N. Govinda Rajan, Shri U. B. Tripathi and Shri S. D. Sharma for useful discussions during the preparation of this article.

References

1. Sources and Effects of Ionizing Radiation, Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), United Nations, New York, 1993.
2. Recommendations of the International Commission on Radiological Protection, ICRP 60, 1991.
3. International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna 1996.
4. Atomic Energy Act 1962 (33 of 1962), September 15, 1962.
5. Radiation Protection Rules 1971, GSR 1061. The Gazette of India, Part II, Section 3(I), October 30, 1971.
6. Atomic Energy (Safe Disposal of Radioactive Wastes) Rules 1987, GSR 125, The Gazette of India, Part II, Section 3(I), February 28, 1987.

7. Radiation Surveillance Procedures for Safe Transport of Radioactive Materials 1987.

8. Radiation Surveillance Procedures for Medical Applications of Radiation 1989. The Gazette of India, Part II, Section 3(I). GSR 388, dated June 3, 1986.

9. Technical Report IEC 977: Medical electrical equipment, medical electron accelerators in the range of 1 MeV to 50 MeV-guidelines for functional performance characteristics. First Edition, Geneva, Switzerland, October, 1989.

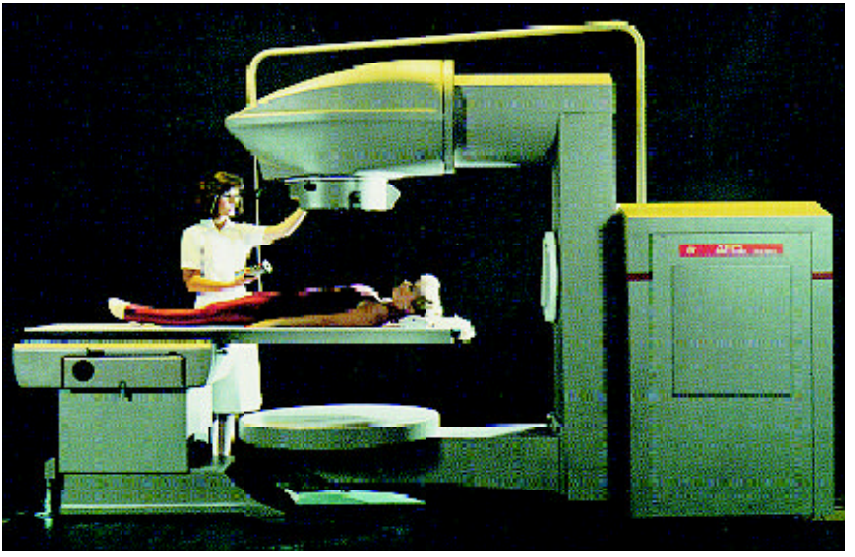
10. Radiological Protection for Medical Exposures to Ionizing Radiation, IAEA Safety Standards Series, No. RS-G-1.5, IAEA, Vienna, 2002

11. Quality Assurance in Radiotherapy, World Health Organization, Geneva, 1988

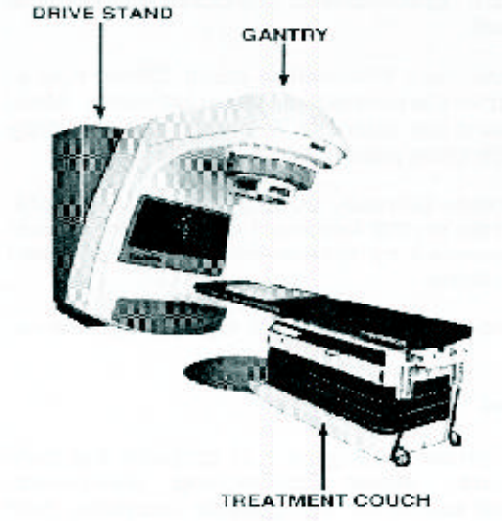
12. Design and Implementation of a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects, IAEA-TECDOC-1040, IAEA, Vienna, 1998

13. G. J. Kutcher, et. al., Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40, Med. Phys. 21(4), 581 - 617, 1994.

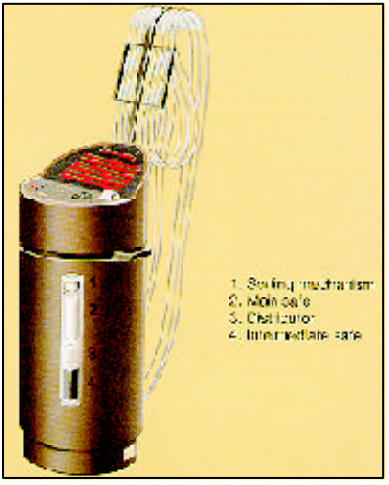
APPENDIX - 1

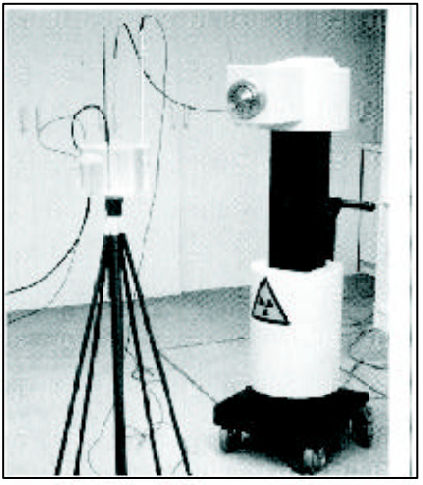


Telecobalt Unit

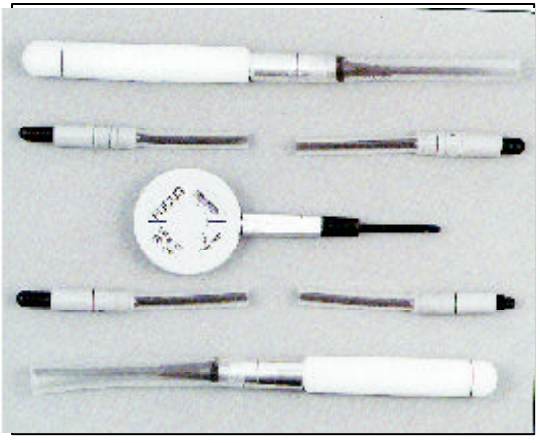


Medical Linear Accelerator





Remote Afterloading Brachytherapy Units



Ionization Chambers

Radiation Surveymeter

Personnel Monitoring TLD Badges