REGULATORY FRAMEWORK: EARLY YEARS

Health Physics Activities

In 1948, the Atomic Energy Act was passed and in the same year the Atomic Energy Commission was constituted. In 1954, the Atomic Energy Establishment Trombay (AEET) was set up.

Raja Ramanna's group at TIFR provided film badge service to radiation workers. In 1956, this service and the newly started radiation surveillance programme were included in what was called Radiological Measurement Laboratory (RML), led by P.N.Krishnamoorthy. A.K.Ganguly who joined in 1955 led the Health Physics Division (HPD). Both RML and HPD reported to A.S.Rao who was then heading the Electronics Group. Shortly, RML became Radiation Measurements Section (RMS) which was reorganized in 1963 as the Directorate of Radiation Protection (DRP) for monitoring non DAE radiation installations.

In 1962, Atomic Energy Act was enacted repealing the Atomic Energy Act, 1948. AEET was subsequently renamed as Bhabha Atomic Research Centre (BARC) in 1966.

Even before the construction of facilities for handling radioactive materials in Trombay in 1958, scientists of DAE were handling small amounts of radioactive materials at the make shift laboratories in Tata Institute of Fundamental Research (TIFR) and at the Bombay Dyeing premises on Cadell road. There were indeed reports of a few safety related unusual occurrences from these activities. For instance in the Chemistry Division at Cadell road, on one occasion while N.Srinivasan and G.S. Tendulkar were working on the production of Uranium metal by fused salt electrolysis, there was a chemical explosion resulting in contamination of many rooms with uranium oxide dust. E.C. Allardice, the Controller, AEET, took S. D. Soman

from the head office of Atomic Energy Commission at Old Yacht Club to assess the situation. He locked all those rooms and handed over the keys to Soman and directed that unless Soman gave clearance, nobody would work in these rooms. Coming from Allardice there could not have been a stronger safety directive.

In another instance in TIFR, there was polonium contamination in Ramanna's nuclear physics laboratory. Soman was again given the responsibility to get the laboratory decontaminated. Incidentally, Soman also served as Chairman of AERB from 1990 to 1993.

Safety Review of Early Research Reactors

When DAE started the design and construction of its first research reactor Apsara in 1955, there was no formal safety analysis report. Designers of various systems of the reactor on their own ensured the safety of the design. They were guided by whatever information that was available in the published literature. Bhabha gave all the decisions and the directives related to the reactor. He used to be personally present to review the design and he also got it vetted by some of his scientist friends from abroad. While there was no formal clearance given for first criticality of Apsara, it had all the safety features that were required in a research reactor at that point of time.

Afterwards, when the second research reactor CIRUS, a joint venture between India and Canada came up, a design and safety report was prepared at the insistence of the Canadian Authority. The report had ten chapters; out of which seven chapters were on various aspects of design and remaining three were on safety. One chapter was on administrative controls including emergency procedures, the second on safety analysis on postulated accidents and their consequences and the third on waste management. These three chapters were prepared jointly by veterans like V. Surya Rao and S.L. Kati from Reactor Operations Division and A. K. Ganguly, S. D. Soman and V.V. Shirvaikar from Health Physics Division. In

one of his overseas visits, Bhabha talked about this safety report to John Cockroft in Harwell and requested N.G. Stewart, Head, Health Physics Division at Dounreay establishment to review the report and give his views. Stewart came to India, went through the document and submitted his comments. He also gave a very useful course of lectures on all aspects of radiation and nuclear safety. Later, Ganguly went to Canada with the final version of these chapters and got them approved. That was how a formal design and safety report for a nuclear reactor was prepared for the first time in India.

For ZERLINA reactor, S.D. Soman, V.S. Prabhakar and N.L. Char prepared a safety analysis report in the format of an AEET report. Some of the major considerations were the ramp reactivity addition, which the system could withstand, the maximum quantity of heavy water, which would be permitted in the storage tanks and the maximum rate at which the control rods could be withdrawn. These aspects were discussed in three well-received papers presented by V. Surya Rao in an IAEA symposium in 1962 on 'Reactor Safety and Hazard Evaluation Techniques'. That was the first time that papers on reactor safety from Indian scientists were presented in an International Conference.

In 1962 Bhabha set up a formal reactor safety committee with A.S. Rao as the Chairman and V. Surya Rao, V.N. Meckoni and A.K.Ganguly as members. This was of course a very senior level committee and had three working groups, one each for Apsara, ZERLINA and CIRUS. Any proposal would first go to the respective working group and then the groups would send their report to the main committee. There was also a program committee which reviewed different proposals for reactor utilization and irradiations in these reactors. These were finally got approved in the reactor safety committee. In addition to these committees, there was also a special committee on reactor control system. Any change in control system of these three research reactors would go to this committee and finally would get vetted with changes and deletions, if any, by the reactor safety committee. So one can notice the careful attention to safety

and existence of a scheme of multi-tier review of safety of reactors even at that time.

Other Nuclear Facilities

In mid 1964 the Plutonium Plant to reprocess irradiated fuel was commissioned. However a formal safety committee for the reprocessing plant was established only in 1966 under the chairmanship of Ganguly. Unlike in the case of reactors, the published data on reprocessing was scanty. So it was considered appropriate to gain some experience with the actual plant systems and their operation before preparing a safety report or any related regulation. By the time the Safety Committee completed its work and submitted the report, the next plant, Power Reactor Fuel Reprocessing Plant (PREFRE) was coming up at Tarapur. Another committee chaired by Soman was therefore constituted to review the safety aspects of PREFRE. He also chaired one more committee which reviewed the large radiological laboratory complex, which included radioisotope, radiochemical, and radio metallurgy laboratories. It can be seen that even though formal regulatory body did not exist at that time, all facilities were being subjected to a thorough safety review.

Siting of Nuclear Power Plants

When the Government gave the approval for construction of the country's first nuclear power station, DAE had to look for a proper site. Soon after selecting Tarapur in Maharashtra in 1960 as the first site, DAE constituted an apex Committee under M.N. Chakravarti, formerly of Railway Board, for selection of sites for future nuclear power plants. Health Physics Division of BARC played a pioneering role in this new task and developed a set of safety criteria for siting of nuclear power plants in the country. These criteria and related concepts were presented in many papers in an IAEA sponsored international conference on containment and siting of reactors and nuclear centres held in March 1963 at TIFR, Bombay. The siting criteria included inter alia the designation of 1 mile (1.6 km) exclusion

zone and 3 miles (4.8 km) sterilization or low population zone. The site selection committee adopted these criteria and selected on this basis, the sites for Rajasthan Atomic Power Project (RAPP) and Madras Atomic Power Project (MAPP). Many of these criteria were not only followed by subsequent site selection committees but also formed the core of the safety code on siting prepared later by AERB.

Radiation Protection in AEET

With the enactment of the Atomic Energy Act 1962, the Department of Atomic Energy received the mandate to enforce safety in all nuclear and radiaiton facilities in the country. The jurisdiction included the nuclear fuel cycle facilities as also the installations using radioisotopes and applications of radiation in medicine, industries and research.

In 1963, the Health Physics Division (HPD) brought out the Manual for Radiation Protection in AEET, a landmark document which served for several years as a standard for radiation protection for all DAE nuclear facilities. In one of the office orders, Bhabha had made it mandatory for all the nuclear facilities to follow this manual. It was a practice in those days, to have the safety requirements issued as office orders either by a Group Director or Director AEET. The health physicists posted in different radiation installations of AEET technically reported to Head, Health Physics Division. They carried out the radiological surveillance of the facilities and took proactive roles in securing from the operators compliance with the safety directives. More often than not, health physicists were also the member-secretaries for the operational safety review committees, unusual occurrence investigation committees and radiation over exposure investigation committees for these installations.

Radiation Protection in Non-DAE Facilities

In 1963, the Directorate of Radiation Protection (DRP) was constituted for monitoring the non-DAE radiation facilities with P.N.Krishnamoorthy as the Deputy Director of DRP. In 1973, both, the

HPD as well DRP were brought under the Chemical Group of BARC headed by A. K. Ganguly. After the promulgation of Atomic Energy (Radiation Protection) Rules, 1971, The Director of DRP was notified as Competent Authority. In 1972, DRP was renamed as Division of Radiological Protection (DRP). In 1973, K.G.Vohra took over as Head DRP. Head, DRP was notified as Competent Authority for the enforcement of RPR 1971. U. Madhavanath later took over as Head DRP in 1987.

The responsibilities of DRP included the radiation protection surveillance of hospitals, industries and research institutes, authorizing users to procure radioactive sources either from isotope Division of BARC or through imports, preparation of safety standards, development of primary and secondary standards for beam therapy, providing personnel monitoring services to all DAE and non-DAE installations and maintaining dose records of all radiation workers. During seventies, there was a quantum jump in the application of radiation particularly in medicine. DRP assisted various institutes in planning their radiotherapy facilities by taking into account safety aspects. Apart from these activities, DRP also developed radiation detection and measuring instruments, TLD for personnel monitoring purposes, biological dosimeters and carried out research in radiation biophysics.

In 1961 DRP started a one year post graduate training course in Hospital Physics and Radiological Physics. WHO supported this initiative by providing relevant books and the University of Bombay recognized this as a Diploma programme. Those who successfully completed this training course or Diploma in Radiological Physics were later recognized by DRP to function as Radiological Safety Officer (RSO) in major radiation installations such as radiotherapy units.

DRP organized several short term (two to four weeks duration) training programmes for medical and industrial applications of radiation. A few two-weeks training programmes for research workers

were conducted on a regular basis. Institutions were authorized to handle radiation sources if and only if they had personnel trained from DRP in the safety aspects of radiation. Several officers from DRP got trained in medical physics and radiation protection in USA, Canada, UK, Belgium and Australia. These personnel in turn helped in disseminating their knowledge by organizing and conducting training programmes at different levels. The regulatory role of DRP received country wide recognition because of the large number of radiation protection surveys and training programmes conducted by DRP.

DRP offered free services in leak testing of radium sources used for brachytherapy in 65 hospitals; the earlier stock dated back to 1930. It offered thremoluminescent dosimetry system for carrying out intercomparision studies on the radiation output of teletherapy units. This programme helped hospitals in delivering accurate doses safely to patients undergoing radiation therapy.

Regulation of Medical Applications of Radiations

DRP has been providing advice and other services to those X-ray installations and manufacturers, who approach them voluntarily. Personnel from DRP carried out radiological protection surveys of a few hundred medical X-ray installations in different parts of India. BARC through agencies under it, had organized regularly several programmes to train radiological safety personnel from different radiation installations. In the case of major installations, the team stayed at the site for several days. They used to prepare detailed reports on such campaigns. This helped the personnel who joined later to understand and appreciate radiation safety principles and practices in medical X-ray installations.

Application of radioisotopes for medical purposes started in the country as early as in 1951. Radioisotopes like P-32 were imported from Harwell, U.K. With the commissioning of Apsara reactor in 1956, the medical use of radioisotopes started increasing steadily.

Diagnostic techniques in nuclear medicine were followed by uses of radioisotopes such as I-131, P-32 in radiotherapy too. Attention was then drawn to radiation safety and related medico-legal aspects.

During early sixties, test monographs for a few radiopharmaceuticals appeared in international pharmacopoeia and in those of some countries. In India the Drug Control Administration considered clearing of radioisotopes under licence number 720. AEET started supply of radioisotopes in diverse forms such as ready-to-use preparations for oral use and for use as injectables, short-lived radioisotope generators to prepare ready-to-use organ imaging agents by intravenous use, cold kits amenable to instantaneous and quantitative incorporation of short lived radioisotopes for organ imaging etc. It soon became apparent that the production, testing and supply of radiopharmaceuticals must fulfill medico-legal aspects related to the manufacture and use of conventional drugs and radiological safety requirements.

The Department of Atomic Energy decided that specialists in the nuclear medicine field should deliberate on aspects related to the safety of premises, patients, workers and public. Director, BARC set up the Radiopharmaceutical Committee on February 23, 1968. The committee was asked to examine the production, practices, controls and the specifications of the radiopharmaceuticals supplied by the Isotope Division. The committee was expected to consider and recommend the incorporation of radiopharmaceuticals into the Indian Pharmacopoeia. The seven member committee had representation from the Directorate General of Health Services, Government of India, Delhi.

Simultaneously, Director, BARC set up a five member Nuclear Medicine Committee. The members were drawn from BARC (Medical Division, Isotope Division, Radiation Medicine Centre), Directorate of Radiation Protection, and the Directorate General of Health Services, Ministry of Health, Government of India, Delhi. The Committee was to

evaluate all proposals for research, diagnostic and therapeutic uses of radioisotopes and approve a list of doctors trained in radioisotope techniques for established diagnostic and therapeutic procedures. Other function of the Committee was to evolve procedures for giving standing clearances to established doctors for using standard products so that no delays are involved for urgent requests. It will, however, examine carefully the applications from every new user and for every new use of medical radioisotopes.

When DAE set up the Board of Radiation and Isotope Technology (BRIT) in 1989, it brought the Radiopharmaceutical Committee under the Board. The Members of the Committee included specialists in nuclear medicine and pharmacy. Commissioner, FDA or his nominee and Drug Controller (India) or his nominee were also made members. The terms of reference were broadened. The Committee approved modifications in procedures and also granted approval to conduct clinical trials before introducing a new product.

Through these procedures DAE achieved overall safety of practices in nuclear medicine, though it may be difficult to find direct legal basis for these early regulatory activities. However in 1977, the Director General of Health Services, Government of India notified that "radiopharmaceuticals" are exempt from the provisions of Chapter IV of the Drugs and Cosmetics Act 1940 as the actual mass of radioactive material in any radiopharmaceutical is too trivial to cause any toxic effect. The frequently used radioactive materials such as Tc-99m have very short half lives; it may not be feasible to study them for sufficiently long periods to evaluate the relevant parameters as is done for conventional pharmaceuticals.

Regulation of Industrial and Research Applications of Radiations

From the sixties, a few institutions started using radioisotopes and other sources in industry. BARC manufactured and sold a few types of industrial gamma radiography exposure devices. Since these sources were potentially dangerous, DRP initiated more formal

regulatory control over them. DRP organized training of personnel at both operating and supervisory levels. Exercising the powers vested with the Competent Authority under the Radiation Protection Rules 1971, Head DRP promulgated the Industrial Radiography (Radiation Surveillance Procedures) 1980. This gazette notification prescribed the mandatory requirements for safe radiography. DRP ensured that trained manpower is available for carrying out radiography.

Nucleonic level gauges, with a few exceptions, used radioactive sources of low activity. These were large in numbers and were distributed in petroleum, paper and textile industries. DRP held short term training programmes on the safety aspects of nucleonic gauges. Institutions could operate the radiation source devices only after they have trained personnel in place.

Isotopes such as P-32, C-14 and H-3 were used as open sources in research mainly in the field of agriculture and hydrology. DRP issued authorizations to receive such sources locally or through import after ensuring minimum safety requirements.

Safety Culture

One might wonder how good was the compliance to safety requirements in the early days of the atomic energy programme in the absence of a formal regulatory body. Thanks to the safety culture assiduously nurtured by Bhabha and sustained by subsequent Chairmen of the Commission, Health Physics Division and DRP were able to ensure a high level of safety in the design and operation of various facilities in the country. Yet another major contributing factor to this healthy situation was the extraordinary respect all had for Ganguly's knowledge, wisdom and guidance. Also whenever there was a safety issue not resolved at a lower level, Rao or Ganguly or Soman did not hesitate to take it up with the Chairman, AEC. So in a sense the safety departments, irrespective of their

name labels, always functioned as independent units from the very early days.

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