IMPLEMENTATION OF ICRP-60, BBS-115 AND THE PATIENT DIRECTIVES IN RADIATION SAFETY REGULATIONS OF TAEK

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Abstract

The use of radiation sources offers a wide range of benefits throughout the world in medicine, research and industry. Precautions are, however, necessary in order to limit the exposure of persons to the radiation that is emitted. The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) were published as IAEA Safety Series No 115 in 1996. This publication marks the culmination of efforts that have continued over the past decades towards harmonization of radiation protection and safety standards internationally. The purpose of the Standards is to establish basic requirements for the protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure. The Standards are based primarily on the recommendations of the ICRP which is a non-governmental scientific organization to establish basic principles and recommendations for radiation protection; the most recent recommendations of the ICRP were issued in 1991. In 1997, the Council of the European Union published a new directive laying down the general principles of the radiation protection of individuals undergoing exposures to ionizing radiations related to medical exposures (Directive 97/43 Euratom). Directive 97/43 Euratom is a supplement on Directive 96/29 Euratom on the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations. The European Directives 96/29-97/43 Euratom and BSS-115 constitute a complete and coherent set of regulatory measures on radiation protection. In Turkey, the infrastructure exists to account for ionizing radiation sources by, for example, a system of licensing, legislative requirements on the user to keep appropriate records and perhaps to report to the TAEK on a periodic basis or, in the case of imported items (including re-export procedures) and customs clearance procedures. The preamble to the Basic Safety Standards states that it is presumed in the Standards that Governments have an adequate national infrastructure in place in order to discharge their responsibilities for radiation protection and safety. In Turkey, the relevant national authority for regulating activities involving radioactive sources is the Turkish Atomic Energy Authority (TAEK). The structure of TAEK and its legislation will be introduced. Radiation Safety Regulation (Official Journal #: 20983) which was issued in 6 September 1991 was revised and issued in 24 March 2000 (Official Journal #: 23999). Revised version of the Radiation Safety Regulation based on BSS-115 and EC Directives include definitions, exemptions, responsibilisation, dose limits (significant decrease in the limits follows the recommendations of ICRP-60), redefinition of controlled and supervised areas, import and re-export procedures of radioactive materials, redefinition of licensing procedures, limitations in import radiation generators used in medicine, quality control, guidance levels of dose, dose rate and activity for medical exposures (including diagnostic radiological procedures, diagnostic procedures in nuclear medicine), dose levels in interventions and guidelines for intervention levels and action levels in emergency exposure situations.

1. Structure

In Turkey, the authorization to determine the limits of responsibility for the principles and precautions and liability for protection against the hazardous effects of ionizing radiations have been given to Turkish Atomic Energy Authority with the Law numbered as 2690. It has been determined that governmental and private associations, organizations and persons who keep, use, import and export, transport, store, make the commerce of radioactive materials and radiation generators must obtain license from the Authority in accordance with Radiation Safety Decree and Radiation Safety Regulation that have become effective in 1985 and 1991 respectively which have been prepared in accordance with, and with the order of this Law.

The requirements of license and permission have been described in the Decree and Regulation. In some other specific regulations that have been prepared in accordance with that Decree and Regulation, special conditions related to the area where the radiation sources are
being used are stated. The radiotherapy regulation prepared in this connection has put into force in 1994. This regulation covers the provisions in compliance with Basic Safety Series 115 (BSS 115) [1] criteria. The current legislation related with radiological safety of TAEK are shown below in figure 1.

By the adoption of above mentioned recommendations, procedures followed in the import, export and licensing of sealed radiation sources in accordance with the application of the regulation have been given below.

a) For the realization of the import procedures, it is necessary that the importing company must obtain license from the Authority. For being granted with this license, it is necessary that the responsible persons and the supplier company must be stated, the compliance certificate of those equipment and sources to be imported to ISO, IEC or equivalent national standards, catalogues and other necessary documents related to the company must be submitted. The authorization certificate from the supplier company that this company can perform these are required and in order to obtain the license for the installation, exchange and maintenance and repair of the sources, the information about the training and experience of the people that will perform these and their medical reports are also requested.

b) The company that has obtained the license to perform such works is also obliged to apply and get permission for each importation process. The permission is being granted after submission of the proforma invoice of the supplier company, production certificate of the source, serial number of the source, the data including the serial number of the equipment and source head or the container and the name of the custom that importation will be made from.

c) The clearance of the source from the custom is only being made possible after the issuance of "transportation permit" which is being prepared as a result of the radiation control of the TAEK experts in the customs. The transport permit is only being granted according to the provisions of "Regulation for the Safe Transport of Radioactive Materials". While this permit is being granted; serial number of the source, emergency case plan, license plate number of the vehicle, name of the driver, personal dosimeter number, the radiation measurement equipment that has to be present in the vehicle is being controlled and the route of the vehicle is being determined.

d) Source exchange procedures is being supervised by the experts after the source reaches its destination.

e) It is necessary that a "LICENSE" must be obtained for the facility where the equipment be put into operation according to the provisions of "Licensing Regulation of the Facilities including Ionizing Radiation Sources for Therapy Purposes in Medicine". For being able to license such facilities; it is necessary that the building in which the source will be present must be granted with civil project approval from the radiation safety view, such facility must employ Radiotherapy Physicists and Radiation Protection Officer and must have all technical equipment that is required. "License" can only be granted to those facilities, after; necessary documents have been submitted the necessary conditions have been complied and quality compliance of the equipment have been approved by the authorized organizations after local measurements and investigations carried out by TAEK experts.

f) For the sending of the used sources to abroad, "Permit for sending abroad" must be obtained by the company licensed for such subject. This permit can only be granted after completion of the inspection at the point where the transportation will start from and following the grant of transportation permit.
In Turkey, a wide range of sources of ionising radiation are used in medicine, research and industry. These include X-ray equipment, sealed gauges containing radioactive materials which are used in industry and liquid radioactive materials used in medicine. While many uses of ionising radiation are clearly beneficial to society, there is an inherent risk associated with any such use.

The primary role TAEK is to ensure that these risks are kept to a minimum through its system of licensing and inspection. Turkish legislation prohibits the use of radioactive substances, irradiating apparatus and other sources of ionising radiation without an appropriate license.

2. Legislation

In general, Turkish legislation governing the use of ionising radiation is derived from European Directives which in turn are based on the recommendations of the International Commission on Radiological Protection (ICRP). The ICRP was established in 1928 and its recommendations, while not mandatory, are highly influential internationally. In 1977 the ICRP published general recommendations on the conceptual framework of radiation protection, based on the following three key principles:

1. **Justification** - the process of showing that a particular use of ionising radiation produces sufficient benefit to the exposed individuals or society to offset the radiation detriment it causes;

2. **Optimisation** - the process of keeping all exposures as low as reasonably achievable, economic and social factors being taken into account; and

3. **Dose limitation** - the process of keeping the sum total of all relevant doses received whether by workers or members of the public within specified limits.
The publication of these general recommendations, commonly referred to as ICRP 26, led directly to the adoption by the European Community in 1980 of Directive 80/836/Euratom (subsequently amended by Directive 84/467/Euratom). This Directive laid down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation and is commonly known as the Basic Safety Standards (BSS) Directive.

The provisions of the 1980 BSS Directive were implemented into Turkish Law by the Radiation Safety Decree published in 1985 and Radiation Safety Regulation published in 1991.

These two statutory instruments provide the framework for the TAEK’s licensing system and detail the general radiation protection requirements for all users of ionising radiation. Particular uses of ionising radiation which are covered by additional legislation include dental exposure, radiotherapy regulation and shipment of radioactive substances.

As a result of a continual process of reappraisal, ICRP recognized during the 1980’s that the risks of exposure to ionising radiation were greater than had previously been thought. ICRP published new general recommendations in 1991, known as ICRP 60 [2], which updated the standards in ICRP 26 and further developed the conceptual framework.

In particular, ICRP 60 distinguishes between practices (activities that increase human exposure) and intervention (actions taken to decrease human exposure in an actual situation). Practices cover the uses of ionising radiation already referred to such as medical uses etc. An example of intervention is the actions taken to reduce exposure in the aftermath of an accident. The principles which apply to practices, where the risk of exposure can be controlled, are different to those applying to intervention. In the latter case, a balance has to be struck between risks arising from the existing exposure situation and the risks involved in intervention measures taken to reduce that exposure.

In 1996 the European Commission followed up the changed standards in ICRP 60 by adopting a revised BSS directive (Directive 96/29/Euratom). In Turkey, the implementation of the BSS Directive to the legislation result in the following changes [3];

- Use of the new ICRP concept of practices and intervention,
- Explicit treatment of natural radiation sources,
- Explicit treatment of “intervention” which includes emergency preparedness.

The revised Radiation Safety Regulation to implement the BSS Directive was published in 2000. Under the EURATOM Treaty, the European Community is required to establish uniform safety standards for radiation protection. This is done by means of the Basic Safety Standards Directives which establish safety standards to protect the health of workers and the general public against the dangers of ionising radiation. These directives form the basis for radiation protection legislation in all Member States.

The Directive does not apply to exposure to radon in homes, to naturally occurring radionuclides in the human body, to above ground exposure to radionuclides in the undisturbed earth’s crust or to cosmic radiation at ground level. A feature of the Directive is the flexibility given to Member States in its implementation. This can be illustrated by a few examples. Firstly, while the Directive includes a list of practices which must be subject to prior authorization, Member States have been given freedom to extend this list. This means
that, in Turkey, no major changes will need to be made to the current licensing system. Secondly, while the Directive lays down a limit on effective dose for exposed workers of 100 millisievert (mSv) over a period of 5 years, subject to a maximum dose of 50 mSv in any single year, Member States may decide on an annual limit. For members of the public, a dose limit of 1 mSv in one year is laid down. However, in special circumstances, a higher dose may be authorized in a single year, provided that the average over five consecutive years dose not exceed 1 mSv per year. This has already been given effect to in Turkish legislation, as annual dose limits of 20 mSv for workers and 1 millisievert (mSv) for members of the public were laid down in the revised Radiation Safety Regulation.

3. Conclusion

Finally, with regard to work activities involving significant exposure to natural radiation sources, there is a good deal of flexibility but specific to be taken by Member States are laid down. These include the identification of work activities which may be of concern, estimation of exposure, implementation of countermeasures and, if required, the introduction of radiation protection procedures in workplaces.

References