ON THE RELATIONSHIP BETWEEN USER SURVEY AND CENTRAL ADMINSTRATION VIGILANCE IN THE MEDICAL USE OF RADIATION IN ITALY. REPERCUSSIONS ON THE APPLICATION OF THE ALARA PRINCIPLE.

M. Marengo[(1)], C.Pettinato[(1)], S.Boschi[(2)], C. Bergamini[(1)].

(1) Medical Physics Department, S.Orsola Malpighi Policlinic Hospital, Bologna, Italy

(2) Nuclear Medicine Department, S.Orsola Malpighi Policlinic Hospital, Bologna, Italy

Introduction

The ALARA principle is appeared in the Italian legislation in 1995, with the new law intended to enforce EU directives 80/836, 84/467, 84/466, 89/618, 90/64, 92/3 and to supersede the set of rules published in 1964 and following years. The 1995 law had to be modified several times up to the year 2000, to take account of directives 89/618, 90/64, e 96/29 and to correct for inaccuracies and misinterpretations.

After a few years, it starts now to be clear that a fruitful application of the ALARA concept can be limited by the concurrency of several factors, that will be discussed in the following with particular regard to the medical field of use of ionising radiation.

The process of rule making

Laws and technical rules in Italy are mainly written by experts form National bodies / Agencies (APAT, the Agency for environmental protection, ENEA, the New Technologies Agency, ISS, the National Health Institute, ISPESL, National Institute for Prevention and Safety of Labour, CNR, the national Research Council etc.). While general competence of these Institutions and the high qualification of their experts is not in discussion, it should be noted that there is not the feeling that users can give an useful contribution in the process of formulation and wording of new laws.

Scientific Associations as well as relevant institutions (Universities, Industries, leading Hospitals) are not involved at all; furthermore, a new law is published after several checks and discussions, but these steps are performed only “inside” the National Ministries and with some involvement of Regional Governments. There is

not an official publication of a draft text of a new law, in order to make possible a wide and open discussion on the new indications and to prevent possible misinterpretations or the risk of over or under ruling in specific fields of use.

New technologies, like publication of a draft on the Internet site of leading Ministries / Agencies, will allow a wide consultation of a great variety of users, Institutions and Industries. The praxis of open meetings for discussion, like in the USA, will allow for a formal mean of consultation and for delimiting the field and time of public comments. It is quite surprising this means are not fruitfully used in a modern western country; these are not only general points, but they find specific interest as regards the application of a law that involves an optimisation process.

Multiplicity of authorities

If we consider an “A Category” application for use of ionising radiation, there are 8 bodies involved in the process of releasing the authorisation:

- The Ministry of Productive Activities
- The Ministry of Health
- The Ministry of Environment
- The Ministry of Labour
- The Ministry of Internal Affairs
- The Environment Protection Agency (APAT)
- The National Institute for Prevention and Safety of Labour (ISPESL)
- The Regional Government

This may be reasonable for a nuclear power plant, but it seems a little bit excessive in the case, for example, of a 10 MeV self shielded cyclotron for production of PET radionuclides. It is generally accepted that potentially harmful devices, like neutron producing particle accelerators are authorised at a National level, but it is also felt that there is a sort of lack of graduation in the application of the law. For small scale, dedicated devices a review by a technically competent Agency (like APAT) should be enough and a short track for the authorisation should be available.

With the current practice, the time needed for an “A Category” authorisation is about 1 year and, most of all, is not fixed, but may vary. If we consider the cost of sophisticated medical devices, of the order of several Millions

Euros, this means losses for several hundred thousand Euros; and it is worthwhile to note that most part of the Health System in Italy is owned by public money (the State himself or Regional Governments).

Finally, it should be noted that an “A Category” license is required, due to serious limits in the law, also in cases like the use (not the production !) of a few hundred mCi/day of ^{11}C ($T_{1/2}$ = 20 min).

Lack of recognised models for demonstrating compliance

The quantitative assessment of compliance and optimisation will be greatly helped by the existence of a shared base of models to evaluate exposures of both workers and general public in specific situations, like foreseeable paths of exposure and radiation accidents. As an example, we can consider cases as the production of ^{41}Ar in the air of the vault of medical accelerators or and uncontrolled release of radioactivity in the air.

The current practice is to make reference to papers published on scientific journals; these are a sort “unrecognised”, informal, models. A user is not obliged nor guided to use a predifined model, and different users can reference different methods of calculation for the same situation / accident.

This means that, starting from different bases, different users can reach variable result in terms of optimisation; moreover, Inspectors reviewing technical documents in an application file, should carefully check every kind of calculations, since there is not guarantee that an already validated model has been used.

This is quite different compared, as an example, to the USA, in which validated models are freely distributed and are recognised by the federal administration (e.g. COMPLY, to evaluate continuos air releases, HotSpot to make previsions in the case of accident release or fire, etc.). A user can then evaluate compliance of his application using the base model and eventually give a justified explanation only for specific conditions or variations to the base model.

Monitoring an authorisation procedure

Once a user as presented an application for an authorisation for an “A category” employ of ionising radiation, he is not informed about who are the Inspector / s that will review his file. Given also the already discussed multiplicity of Administrations / Agencies involved, this causes serious problems of communication between users and reviewers. Even when a users knows who are the correct contact persons, he has not any guarantee

that he can easily reach them; it is worthwhile to note that no Ministry in Italy publishes (e.g. in their Internet sites) a directory of e-mails or phone numbers of their functionaries.

There is the need for a “single counter” to which address any sort of questions, requests of information and to which submit files and technical documentation. Complexity in the organisation of the public administration should be “transpartent” to the user, that is not requested to possess the skills of a blind navigation in the mists of national bureaucracy.

Qualification and training

Laws regarding radiation protection contain a detailed description of the knowledge and skills required to be admitted in the board of Qualified Experts. The curricula of study, the background experience and the modality of examination are wide and variable enough to possibly give rise to incoherent application.

In example, an Hospital Physicist with more than 10 years experience and already qualified in the board as regards radiation protection issues related to X-ray tubes and unsealed radioactive sources, willing to acquire the qualification needed for neutron sources like Linacs, can be discarded after an examination regarding only decommissioning of nuclear power plants. Examinations will probably be more effective if specific to the field of interest, leaving to the market the opportunity for Hospitals, Industries etc. to choose the Qualified Expert with the best curriculum and background to fulfil specific needs.

On the other hand, there are not formal requirements for the background and qualification of National Agencies Inspectors. Recruitment is made on the basis of general rules for public employees and training is mostly based on working side by side with already experienced Inspectors.

There is to note that even for experienced Inspectors, the skills gained in the field of industrial use of radiation can not be adequate in the medical field, and vice versa. Moreover, there is a lack of a flexible tool, like “informal” inspections, that are now excluded in Italy. These could instead be really useful, in several ways: for instruction of new Inspectors and also for continuous education of existing Inspectors. The concept of Continuous Education is now widely used in the medical field, and in most European countries, is also a mandatory requirement. Is then difficult to understand how users and radiation protection experts in the medical field are obliged to demonstrate the maintenance of up to date knowledge, while Inspectors deputed to review their operation are not.

Conclusions

Radiation protection laws are enforced in Italy by more than 40 years, and standards of radiation protection for workers and population may be considered as satisfactory. After the introduction of the ALARA in the 1995 revision of the law, several problem remain in the relationship between users and National Administration. In the present era, that combines limited resources and increasing expectations of health care, these may be a serious limitation in the rapidly evolving field of medical application of ionising radiation.