The Problems of Regulation of Natural and Medical Exposure

Challenges and limitations from the regulatory point of view

Karla Petrová

The State office for Nuclear Safety,
The Czech Republic
Radon – Czech approach

- open communication since 1989 governmental engagement
- legislation – establishing reference levels and also „limiting „ levels for dwellings and water,
- screening,
- prevention,
- schools, kindergartens, public water supply control – state budget,
- public information,
- research and development,
- financial support from the state budget under pre-defined conditions
From the regulatory point of view there are still several problems to figure out for achieving effective and reliable system of the indoor radon exposure control.
Regulatory Issues and Concerns - indoor radon

- co-operation with the building offices (under Ministry of Regional Development) - priorities
- potential conflict with the private ownership
- explanation of the sense and use of the reference values (difference for old and new buildings)
- control of the effectiveness
- measurements in newly constructed buildings always under discussion – the short term measurement before the use of the building could be misleading, if long term measurement during first year of the use is performed what to do when higher than reference level is estimated and who is thereafter responsible for further steps
- responsibilities – owner, designer, constructor?
- influence of the real estate market – positive way?
- another problems identified – the remedial measures are not effective enough in the time, their lifespan is estimated in average for 15 years, people often switch off for example ventilation because of noise or saving power or saving heat energy.
Regulatory Issues and Concerns - indoor radon

- the control of the companies licensed for the measurements of the indoor radon and for the determination of so called radon index of the soil
- the control of an effectiveness of measurements of the indoor radon
- in situ inspections
The objectives

- Reduction of the individual doses or collective dose??
- There are still two main different opinions – we want to reduce the individual risk to the acceptable level given by the reference levels or we want to decrease the collective dose to the “reasonable” level (what is reasonable level here? – the level determined by cost-benefit analysis within the optimization process?).
The future Czech national radon program will reflect the experience of the past years and will be modified mainly by the re-arrangement of the priorities. It will be focused notably to the prevention and to the public communication. The accessibility of the qualified and reliable measurements will be ensured by the government. The effectiveness of the whole program will be regularly performed including the independent assessment.
But still we are facing unsolved problems

- However it is not only about the legislative and regulatory framework, it is mainly about the persuasion of people for cooperation.
- **Without this it will not work!**
- And what is the way of appropriate convincing – such which will cause an appropriate interest – and will be related to the real risk?
- There are another essential actual risk in the society which shall be address by the society and the priorities must be set up for the effective and realistic distribution of limited resources (holistic approach).
- But the adequate public information campaign could lead to the responsible behavior of people.
Conclusions

- We have to go step by step and mainly initiate the public education, explain the consequences and to try to catch the interest of the people to this problem so they will themselves interested in the improvements – necessary co-operation with professional sociologists.

- In my personal opinion and with respect to all problems described above – it is not so important at the moment which values we will choose as a reference levels – the most important is to convince people to be reasonably aware of the radon, to understand it and to increase the number of finalized remedial measures and also numbers of new buildings finalized with appropriate and effective radon protective measures.
Medical exposures

- The regulation of medical exposure – current approach in the Czech Republic (the same almost in each country with some modifications):
- Application of basic principles of radiation protection – justification, optimization
- Almost all practices authorized
- Requirements for documentation
- Requirements for tests and control of sources
- Licensing and control of companies performing tests
- Requirements for the quality assurance
- Diagnostic reference levels
- Clinical responsibility for the correct performance of medical exposure
- Radiation protection expert, Radiation Medical expert
- Radiological standards
- Evaluation of dosed to the patients – registration of parameters of exposure
- Assessment of numbers of examination
- Clinical audit – external, internal
Medical Exposures

- ...and still it is not enough!

Or is it?
Medical Exposures

- What are the indicators?
- The increase number of procedures?
  It is not a natural development and progress of society? Can we evaluate the benefit from all these exposures?
Medical Exposures

- The main problem from the regulatory point of view – the ideal system described above is not of course fulfilled in the practical life.
- There are technical and clear medical aspects of medical exposures where the competence is not clearly defined and where nobody feel the real and final responsibility and those are mainly – justification of individual medical exposure, clinical responsibility, radiological standards, clinical audit.
- When responsibility is not clearly determined very often finally nobody is taking care – what is of course general observation in the life!
Common questions

- The role and rights of radiation protection
- The regulation to the acceptable individual dose or collective dose
- Risk Communication
- Increase awareness of exposed individuals – how, not to provoke hysteria and inadequate reactions
- Soft issues for regulator – not education how to manage
New Methods

- New methods are always developed, often they are very effective, helping to the treatment, saving lives.
- What is the role of radiation protection here? Are we able to contribute to this part of medical exposure? Or we have to focus only to the technical aspects – to control the technical appropriateness of devices used, to ensure periodical controls of technical parameters, to set up diagnostic reference levels, etc…
- But we all know very well that the increase of dose to the population is influenced mainly by the increase of numbers of exposures. And again we have here this question – what is our main goal here? To keep the doses to individual on acceptable level or to regulate collective dose? But to which level? What is acceptable?
New Devices

- New devices don’t always mean a lower doses but potentially if they are used appropriately under all recommended conditions the doses could be much lower.

- The complexity of devices nowadays and complicatedness of its operation, maintenance, service brings the difficulties to the medical staff – they change the parameters of the exposure and they very often don’t understand the basic relationship between the physical quantities. As the result we can see non explicable several order differences in dose for the same procedure and the same device in different workplaces - the doses are not optimized and unnecessarily high.
Dose evaluation and comparison

- There was an idea discussed in reality – to publish the results of dose evaluation for set of standard procedures in all medical workplaces – and it was of course refused because the added value of such approach was estimated almost as a minus value – public cannot understand it and this approach could cause only confusion. This comparison could of course be very valuable for regulator however it is not easy to obtain such complex results – they are often the results of some studies or clinical audits – but there always is condition that such data are private data and there is no possibility to give them to the third party.
Statistics

- But as was already mentioned above the regulation of numbers of exposure performed seems to be the most effective approach for the regulation of medical exposures.
- But even we have a nice and complex statistic and distribution of procedures related to the sex, age, etc – what we can do except very nice graphs we can produce and present?
Registration

- Some part of exposures could be saved if effective system of registration of examination is on the place. IAEA now develops a radiation card for registration of each medical exposure of individual. Some big hospitals and consortium of hospitals they have an electronic system enabling to see all information about patient and his examinations to all doctors with the access to the system.
Studies

- We also observe more and more medical studies where ionizing radiation is used. Very often IR is not a primary interest – the examination only serve for the searching of appropriate patients with certain illness in certain stage defined for study. It can happen that there is a need of 300 patients for the study but exposure is delivered to 1000 of them – is this justified?
Asymptomatic persons

The examination of asymptomatic persons is another story mentioned also above already – who has a right to refuse such examination?

Always there is a possibility to find something wrong what could be very well curable if the care will start as soon as possible.
We all observe the increase numbers of CT procedures – in the Czech Republic 2,5 times during last 15 years. We have organized the seminars with physicians and we have discussed the problem. The message taken was that the physicians really have a lack of relevant information concerning the risk related to the examination, they don’t understand it well and they don’t know how to communicate it with the patients. Some of them took the personal initiative and they started to do something – to evaluate doses, develop real (it means realistic and practical standard procedures not only used for the satisfaction of regulator but useful mainly for themselves!), looking for tools for the dose reduction to the patient or to the staff. But these are rare cases.

The role of radiological assistant and also radiological physicist are always underestimated.
Discussion

- The discussion with the management of big hospitals (with the presence of highest management of regulator also) – an open discussion about all problems they face – about their limitations, fears, reasons, etc.. The discussion was very good but the conclusions were skeptical and not very positive.

- The physicians know very well that many of procedures need not be performed, but they adopt a buck passing posture because of their fear of court – what is realistic more and more – patients have own society for their rights protection with own capable lawyers.
Proliferation

- What was alarming – an unofficial lobby information about the internal prescription of certain number of procedures (per day or per month) because of financing from health insurance system. The pressure of manufacturers and distributing companies is enormous – the purchase of devices is rewarded – the companies are racing in attractive offers! X-rays machines and CT are sometimes as a gift to the purchase of very expensive complex equipment.

- The control of proliferation of medical devices is as a requirement in EU BSS however it was deleted in the last proposal because the most of countries were not able to implement it!
Health Insurance

- Another problem – the rules of payment from the health insurance system. The examination made using MR is 2.5 times more expensive than CT.
- Despite of this we wanted to enforce the support of this alternative technique from the side of health insurance companies. Unfortunately recently there are some studies questioning the health risk from MR for staff and patients as well. This is of course completely against our effort. But it is clear that the role of HIS is potentially important because where are money there is also power.
Conclusions

- The problem of regulation of medical exposures is the problem with highest priority and with highest difficulty for radiation protection.
- The situation is influenced by many factors also out of the scope of radiation protection. The regulation of exposures is generally against the effort of physicians who are crucial players on the scene here. The physicians when evaluating risk and benefits of the examination put logically a significant weight on the side of benefit having on mind the best, effective and successful treatment of the patient. IR is one of the tools how this goal could be achieved.
- The consensus we have found in the discussion with them was the need of further and effective education of all physicians participating in medical exposure performance – referral and radiologist as well. It is necessary to prepare simply, understandable materials explaining all important aspects of medical exposure, stressing also the alternatives to the examinations using IR.
- And to discuss – to organize seminars, workshops, conferences. To introduce basic course on radiation protection and risk communication into the schools!
The results of the X-ray

**Patient:** Doctor, what does the X-ray of my head show?

**Doctor:** Absolutely nothing!
Conclusions

● There is no doubt that the science and progress and development has to be reflected in the RP and RP regulation practice, however, it has to be done sensitively and carefully so that the current system is not disturbed. (what we currently can observe sometimes – standards and regulation are impatiently waiting for quite fresh scientific results to absorb them without taking time for evaluation of all possible practical consequences)

● The activities on the international level have to be planned effectively and in co-operation with the aim to avoid the overlapping which caused overwhelming burden for involved parties.
General Remarks of Regulator

- Regulator is in the case of medical and natural exposures regulation facing several problems as described above. As a principal problem we could see the appropriate risk communication.

- We observe here strong shift to the soft issues which are as important as technical issues but not as readily solvable.

- We deal here with safety management, social and human factors, communication issues, … and at the end we stay in front of the establishment of effective and complex legislative framework where we try to balance between prescriptive and goal setting legislation.
General Remarks of Regulator

- In any case we have to maintain the historical and logical coherence. Only this can help us minimize the danger of the loss of trust of the public to the role of regulators.
- The trust is very difficult to build up as we know very well and especially when ionizing radiation is concerned people are very attentive. This fact, even if by specialists sometimes perceived as irrational, has to be taken into account always when communicating with public the risk connected with the exposure to ionizing radiation.
- The effectiveness of RP regulations is closely tied to the openness and independence of their actions. Greater openness should help RP experts to improve public understanding of RP in general.
- General public is “result oriented”, it does not care about sophisticated discussions of experts. On the other hand, it would not be wise to underestimate ability of general public and interest groups to judge on the content and real value of any regulatory action and decision.