SOME CONSEQUENCES OF NEW SWEDISH REGULATIONS IN THE MEDICAL SECTOR

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1. INTRODUCTION:

Initiatives within the European Union have been taken in order to harmonise radiation protection for workers, including those in the medical sector. These efforts resulted in a today well-known directive [1]. The Swedish Radiation Protection Authority (SSI) is responsible for the implementation of this directive into a national legal framework. In the years 1998 to 2000 four new regulations regarding the workers in medical use of ionising radiation has been issued from SSI [2-5].

At present the hospitals are implementing the regulations, in some cases after prompting from the SSI, into the daily routine and into the quality assurance systems. SSI has to evaluate the effect of the regulations and how they are followed; this is done to a large extent by on-site inspections and to a minor extent by enquiries sent out to all licence holders. SSI is regarding inspections as an important tool. Discussions between the hospitals and SSI are also carried out in different forum.

2. A SHORT DESCRIPTION OF RECENT CHANGES IN THE SWEDISH LEGISLATIVE FRAMEWORK

The regulations issued in 1998 concerns among other things:

- categorisation of work and workplaces
- dose limits for workers and others
- measurements and reporting of doses to the authority
- medical surveillance of worker

These regulations are not exclusively produced for the medical sector and no detailed instruction for the use in this area was issued. The categorisation of workers, where the definition of category A and B is adopted from the directive, has been performed locally in the hospitals. The definition of category A has been introduced in regulations issued in 1996 [6] concerning external workers. Until now this regulation has been considered to be not relevant for the medical sector where it was assumed that external workers do not exist.
The regulation [2] gave some indication on for what types of activities the personnel should be considered to belong to category A, although not comprehensive; e.g. fluoroscopic investigations in diagnostic radiology and therapy with sealed sources.

The regulations concerning dose limits were only changed slightly, e.g. the dose limit for lifetime dose was removed. The annual dose limit for the effective dose is 50 mSv with a limit for five consecutive years of 100 mSv. Special dose limits exist for students and trainees aged 16-18 and special dose limits also exist for the lens of the eye, skin, hands, forearms, feet and ankles. New dose limits for pregnant personnel were also introduced in order to strengthen the protection of the unborn child. After pregnancy is noticed the work shall be planned in such a way that it is unlikely for the foetus to receive an equivalent dose above 1 mSv. In former regulations it was required that the effective dose to a fertile woman should not exceed 10 mSv in two consecutive months because that would prevent the foetus for undue high doses during the first two months of pregnancy. The new regulations may imply that measurements have to be performed in order to ensure that this limit is not exceeded. Now the pregnant woman has the right to be transferred to work that does not involve exposure to ionising radiation during the remaining time of the pregnancy. Female workers of appropriate age should be informed about the risk to a foetus when it is exposed to radiation.

Today measurements of personal dose have to be performed with dosimeters from an authorised laboratory. At present Sweden have 11 such laboratories. The sites were inspected and approved for measurements of external dose in photon fields. When these inspections were carried out a specific checklist of requirements was established, e.g. concerning the organisation, routines for calibration and dose determinations. A specific survey was also carried out in order to test the laboratories' ability of determining $H_p(10)$ in different dose intervals [12]. For some of the sites the angular response of the dosemeter was also tested. After this survey a number of laboratories had to alter their procedures slightly, for example a commonly occurring data programme fault was discovered. Also a national dose registry was established where special considerations apply when personal

doses from the medical sector are reported. Dose measurements for category A workers shall be reported and registered into the record, but also measurement for category B workers are registered. In addition, the employer must keep records of all measured doses.

The fourth statute regulates the medical examination for every person categorized as A. A specific list of examinations that should be considered exists but it has to be taking into account the nature of the work the employee has to perform. Some examples of examinations to be included: lung function, heart function, and kidney function or look for signs for skin disease, neurological disease, alcohol or drug abuse and diabetes. After this examination the person is considered fit or unfit for work.

In the year 2000, five additional regulations were issued [7-11], dealing exclusively with the medical sector, as a consequence of the Medical Directive [13]. Although all these regulations are not directly dealing with the radiation protection of the staff there are indirect consequences. Dose reduction for patients means in most situations also dose reduction to the staff. Education and training, quality assurance and requirement of competence in radiation protection for the patient will doubtless be of benefit also for the radiation protection of the staff. These statues comprise among other things:

- quality assurance
- the organisation of radiation protection
- radiation protection education of the personnel

None of these three issues above are of course new for the hospitals, but in the new regulatory format they are treated in a more stringent way, i.e. good documentation, a quality assurance system for the radiation protection work including schemes for the organisation and education for the personnel. Such documents included in the QA system have to be revised regularly. SSI particularly emphasised education in radiation protection for personnel operating equipment, especially x-ray equipment inside and outside the department of radiology. The hospitals also must have a documentation of the organisation for the radiation protection work, i.e. listing who is responsible for what.

In order to analyse the consequences of these new regulations in the hospital SSI's inspections after the year 2000 included issues dealing with all these regulations. SSI has also encouraged discussions of these topics in national workshops.

3. SOME OBSERVED CONSEQUENCES OF THESE REGULATIONS IN THE MEDICAL SECTOR

The category classification has been performed in different ways in different hospitals, which was discovered by on-site inspections. In some hospitals no personnel at all is categorised as A, in others all personnel working with ionising radiation in radiology, therapy and nuclear medicine is in category A. Of course everything in between also exists. For one group there seem to be agreement between the hospitals, those working with preparation of radiopharmaceuticals or with investigations of patients, they are mostly placed in category A.
The ground on which classification is made differs also. Mainly the classification relies on studies of old records of personnel doses. Another factor is the risk for accidents, e.g. in external therapy and in nuclear medicine. A third factor, not really acceptable, is taking into account the fact that category A workers shall be monitored regularly and the management or personnel are insisting that all personnel is entitled to wear a dosimeter and therefore everybody is placed into category A. A forth factor is that the management wants to minimise the use of dosimeters and therefore all workers are assigned to category B and only a few are monitored to ensure the correctness of the assignment.

It is not easy to estimate whether the number of persons wearing a dosimeter have increased or not. It must be taken into account how persons are monitored and the number who don't wear a dosimeter. Measurements have to be performed from time to time to check the appropriateness of categorising the personnel, and when new techniques or equipment are taken into use the categorisation could change. Also measurements of organ and partial body doses have to be performed. In some cases a large number of persons are wearing dosimeters regularly despite that they are category B, and in some cases measured doses from category B workers are reported to the national dose registry.

The categorisation of workplaces did also vary between different hospitals but not as much as the categorisation of workers. The largest discrepancies seems to be the categorisation of workplaces with non-stationary equipment, e.g. in operation theatres.

Dose limits for pregnant women have been discussed comparatively little, and it is very important that all becoming pregnant know all about these regulations. The number of women wanting to change workplace is to our knowledge also limited; the level of knowledge by the workers could influence this.

Recorded personnel dose could now be compared with other data. In Figures 1 and 2 the Swedish values are compared with Danish values, the latter being made available by the Danish Radiation Protection Authority on the Internet. The number of persons reported to the Danish authority is much larger than the number in Sweden, although the number of inhabitants in Sweden is nearly twice the number in Denmark and the number of medical examinations in Sweden is also about twice the number in Denmark [14]. We have to be careful when comparing mean effective dose or collective dose in the medical sector.
Lack of documentation, including the absence of valid radiation protection organisation, is a frequent remark after an inspection has been carried out. The lack of education for personnel in radiation protection is also frequent especially for those where radiation protection is not part in the professional education.

4. SPECIAL CONSIDERATIONS OF THE CONSEQUENCES

All these regulations could be seen as, and in some cases are seen as, unnecessary bureaucracy. It is therefore essential to raise the level of consciousness about the underlying causes of these regulations. This makes great demands on the authority to be very comprehensive when communicating these regulations to the hospitals. This is very demanding for the authority; in order to communicate it has to be updated on all the activities concerning ionisation radiation in the hospital.

The categorisation of workers is an opportunity for the hospital to analyse the contribution of different activities to the personnel dose. There is a risk that a personnel that is not categorised as A workers is forgotten. The compliance with dose limits for partial body and organ doses must be checked, but it might be forgotten. All together the regulations concerning categorisation have been highlighting the personnel dose again in the medical sector. The question of external workers have to be considered due to a larger number of workers, especially in x-ray diagnostics, not employed by the hospitals but by other companies. This will emphasise the presence of a functioning quality system to secure e.g. that locally radiation protection issues are known.

The dose limits could work in contradiction to the ALARA concept. To our knowledge only in exceptional cases the measured dose have been approaching but not exceeding the dose limits. One suggestion that have been raised is the implementation of the concept dose constraints for different activities and procedures in the medical sector [e.g. 15]. One could even suggest reference levels for different procedures. If the work is done efficiently the dose to the personnel is not over a certain level. A concept that has already been introduced is the system of reference dose levels for patients in nuclear medicine and diagnostic radiology [16]. Implementing dose constraints or reference levels for occupational dose has not been discussed at SSI.

The authority also has a new tool, the national dose registry, for analysing trends in the personnel dose values. However care have to be taken when analysing the results because of the differences between the hospitals' routines for reporting concerning e.g. the number of workers reported.

The requirement of medical surveillance could also be contra productive to the ALARA concept because of the different interpretation of the purpose of such investigations. There still exists an opinion that the main purpose is to detect radiation damage. Some organisations have not carried out these examinations yet despite the medical sector has both knowledge about and possibilities to carry out medical examinations.

The requirement for proper quality assurance is also a basic concept in different organisations today. The documentation of the radiation protection organisation is essential when organisational structures both in the public and private sector are changed. This is particular important when changes in the labour market are seen or suspected, e.g. the increased mobility of personnel between hospitals increasing the number of new personnel in the hospitals.

Education of the personnel is of course a core in all radiation protection.

5. FUTURE WORK

A national promotion considering the education plan and execution of the education for personnel using x-ray equipment outside the radiology department has been planned. Inspections are of course an important part of our

activity but only a limited number of hospitals are visited each year at present, an increase of this activity involving all licence holders would be more efficient.

SSI is also planning for a more frequent use of the Internet for communication with the licence holders.

A framework for continuous follow up of the reported dose values has to be developed together with a structure for reporting and communicating dose levels to the licence holders.
Additional attention has to be drawn to organ dose and partial dose measurement, both promoting measurements and evaluating the measuring technique.

6. FIGURES

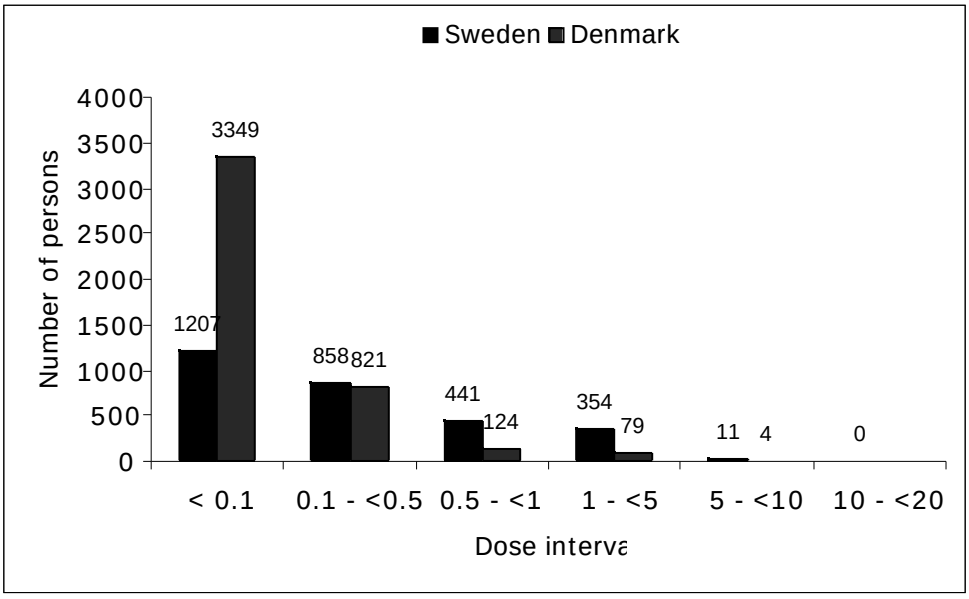

Figure 1. Comparison between Sweden and Denmark, workers in x-ray diagnostics

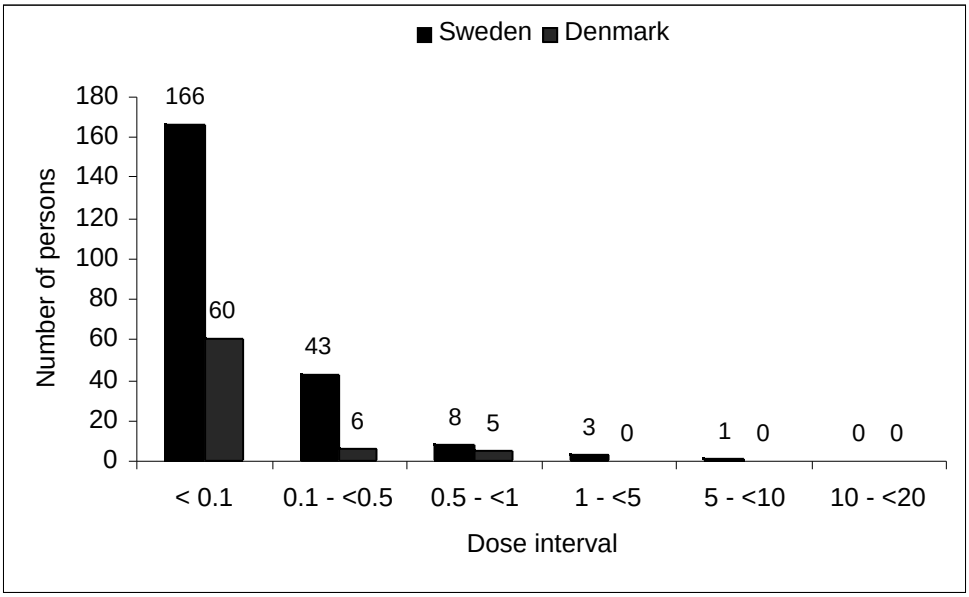

Figure 2. Comparison between Sweden and Denmark, workers in radiotherapy

7. REFERENCES

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3. SSI FS 1998:4 Regulations on Dose Limits at Work with Ionising Radiation.

4. SSI FS 1998:5 The Swedish Radiation Protection Institutes Regulations on Monitoring and Reporting of Individual Radiation Doses

5. SSI FS 1998:6 Regulations on Medical Examinations for Work involving Ionising Radiation

6. SSI FS 1996:3 Regulations on Outside Workers Work with Ionising Radiation

7. SSI FS 2000:1 Regulations on General Obligations in Medical and Dental Practices using Ionising Radiation

8. SSI FS 2000:2 Regulations on X-ray Diagnostics

9. SSI FS 2000:3 Regulations and General Advice on Nuclear Medicine

10. SSI FS 2000:4 Regulations on Radiation Therapy

11. SSI FS 2000:7 Regulations on Laboratory Work with Unsealed Radioactive Substances

12. Lund E, Kyllönen JE, Grindborg JE, Lingborg L (2001) Performance testing of personal dosemeter from eleven dosimetry services in Sweden Rad. Prot. Dosim. 96: 99-103

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