Regulatory Control of Radiological Protection in the medical and research field in Switzerland

Dr. Nicolas Stritt [#], Dr. Philipp Trueb [#]

[#] Swiss Federal Office of Public Health, Bern, Switzerland

Abstract
In Switzerland the handling of radioactive substances, equipment or objects containing radioactive substances, the manufacturing, marketing, installation and utilization of plant and equipment likely to emit ionizing radiation and the application of ionizing radiation and radioactive substances to the human body, require licenses. The Swiss Federal Office of Public Health (SFOPH) is the responsible regulatory body, which issuing licenses for the scope of medical and research field, mentioned above. The office is responsible for the inspection and surveillance of installations, substances, equipment or objects which emit ionizing radiation. The SFOPH is certified according to the ISO 9001-2000 standard and all licensing and controlling procedures are described in a QM manual. The way of dealing with audits, inspections and reports will be described. Several factors will also be presented, as to how to check the achievement of the ALARA principle during radiological protection inspection. The type of inspections undertaken, the periodicity, as well as checking of occupational radiological protection is regulated in Switzerland by laws and technical ordinances. This paper will also deal with the way or means, the SFOPH has, to make workers fulfill the requirements outlined in the different existing laws.

Balancing Advantages against Risks

The SFOPH is one of the Federal Offices belonging to the Federal Department of the Interior (FDI). It is comprised of five specialist units, each focusing respectively on therapeutic products, radiation protection and chemicals, foods and commodities, substance abuse and Aids, and health policy and epidemiology.

According to the federal law of 22nd March 1991 [1] and ordinance [2] governing radiation protection, which also defines the mandate of the SFOPH in this field, "any activity that exposes people or the environment to ionizing radiation may only be practiced, if the advantages gained outweigh the risks involved". This basic rule is intended to protect man and his environment from the dangers of ionizing radiation. It applies to all activities, installations, occurrences and situations which involve some risk of ionizing radiation, and so may gauge increased levels of radioactivity to be released into the environment. In this context, the Radiation Protection Division is the regulatory body and as well as the licensing authority. It issues licenses for installations, equipments and the handling of radioactive substances used in the medical field, industry, research and training, which produce ionizing radiation. It also monitors the compliance of such installations, equipments and handler except in the industry filed to relevant regulations, and ensures that the safety of persons active in this field can be guaranteed. The regulatory body for the industry is the Swiss National Accident Insurance Fund. The nuclear power plants themselves are subject to the authority of the Swiss Federal Council and the Federal Office for Energy. The mandate of the Radioprotection Division of the SFOPH also includes the measurement of radioactivity in the environment. Each year it publishes a detailed report containing the results of these measurements together with information about the level of exposure of the population to radiation. In addition to natural radioactivity, radiation can be caused by human activity or an accident such as the Chernobyl disaster. Although radioactive fall-out from the nuclear catastrophe at Chernobyl is diminishing, in the most heavily affected parts of Switzerland, it is still detectable.

Quality assurance management

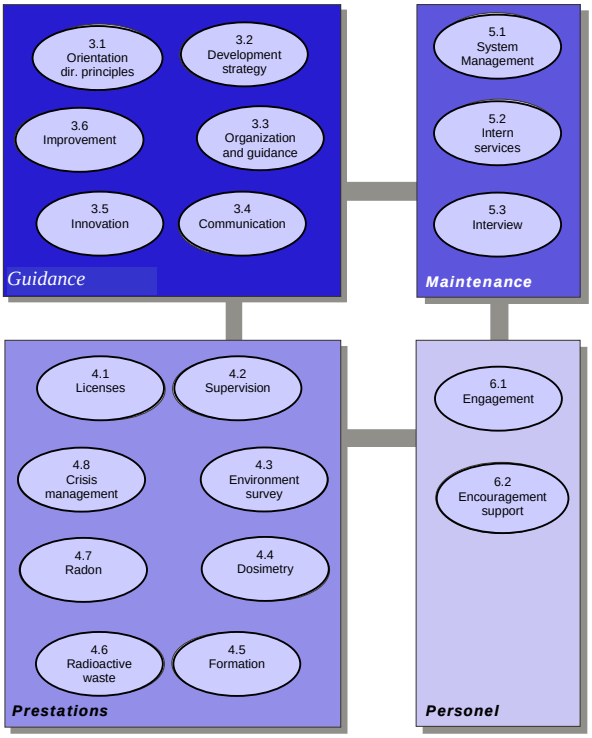
One means used by the SFOPH to control and to survey the radioprotection in the field of research and medicine are the inspections. In order to improve and optimize the quality of the regulatory processes and supervisions and to achieve the lowest dose for patient and personnel, the Radioprotection Division of the SFOPH introduced in the year 2000 a global system of quality management. The entire Division was certified July 2, 2000 according to ISO 9001:2000 (see picture 1) and the measurement laboratory for the radioactivity in the environment was accredited October 5, 2000 according to ISO/IEC 17025.

The willingness to prove the quality of work goes with the acceptation to constantly improve our work. Quality management (QM) is one of these instruments. For the development and introduction of the

quality management system the choice stands as a future solution. The QM system is entirely computerized. The only documentation from the server is reliable. The synoptic table of picture 2 gives a view of the process involved in the QM manual. The process of licensing and controlling as well as the inspections reports used during a radioprotection survey made by the regulatory body are defined as flow charts and registered in the QM handbook. Every inspector uses the same inspection report and therefore uniformity among the inspections is guaranteed.


IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
CERTIFICATE
IQNet and SQS
hereby certify that the organization
Swiss Federal Office of Public Health
CH-3003 Bern
Certified area
Radiation Protection Division
Field of activity
Regulatory Authority
Radiation Protection Service and Information Centre
has implemented and maintains a
Management System
which fulfils the requirements of the following standard
ISO 9001:2000
Scope No: 36
Issued on: 02.07.2001
Validity date: 01.07.2004
Registration Number: 16838-01
Dr. Fabio Roversi
President of IQNet
Theodor Zahner
Managing Director SQS

Picture 1. QM certificate



Picture 2. QM synoptic table

Goals of the inspection

The periodicity and way of dealing with inspections are principally based on the manpower available to the regulatory bodies and on the risk and potential danger of installations or laboratories. The section responsible for the licensing and supervision among the Radioprotection Divisions of the SFOPH contains ca. 12 full time inspectors who are responsible for all installations and companies handling radioactive substances in the medical und research field in Switzerland. Every inspector is in charge of a dedicated region in Switzerland. The number of total licenses for installation emitting ionizing radiation and companies handling radioactive substances in Switzerland lies in the order of 20'000. Every year roughly 3000 licenses are issued, renewed or modified. In general the inspectors make in total roughly 700 inspection in the installation pro year. It is necessary for the licensed installations and companies to have a regular specific inspections and periodical surveys in order to keep a good quality standard in radioprotection. In the development of the survey concept, the risks and potential dangers for patients, personnel and environment were taken into account, so as to set the priorities and to define which installations have to be controlled. The SFOPH is not the only actor responsible for the ALARA principle. The license holder plays also a great role in the application of the ALARA principle in radioprotection in his company.

Survey task

The radioprotection survey in the research and medical field is divided into two categories. On one hand the implementation of the radioprotection laws and directives are controlled directly on-site and the observed discrepancies individually corrected and removed. On the other hand the specifications as well as other useful information will be gathered by means of an administrative survey by exchange of correspondence and forms. The important aspects of the administrative survey are discussed and defined each year in the annual goal of the Radioprotection Division of the SFOPH.

Visit of the enterprises, types of inspections
The SFOPH distinguishes between four types of radioprotection inspections (initial inspection, follow-up inspections, administrative inspections and audits). The periodicity and type of inspections undertaken during the validity of a license for all the companies are listed in table 1 and 2. The four types of inspections are described here after:

Initial inspections
An initial inspection will generally be effectuated after a new installation, the renewal of an installation or construction of new laboratories. This is usually the first time an inspector goes visit a company to check up on the different radioprotection issues. During this inspection not only the apparatus is tested but also the radioprotection plan, the construction plan as well as the width of the shielding and the delimitation of the controlled area. During the inspection, reference values of the RX machine, activity of a source, training of the person in charge, as well as dose exposure of the working personnel are inspected including other things. A full examination is undertaken to check if the installation or laboratory meets the requirements set out in the ordinance and legal articles applicable and to check if the data conforms to what was declared in the license application. All points inspected and results of the inspection are put down in the protocol report and all the breaches are described and communicated to the user. The company is then obliged to fulfill the charges within a set deadline otherwise the license can and will be withdrawn/not issued. The date of the inspection is added to a data base, where all relevant data of the license is registered to ensure a follow-up of the history of the installation during the validity of the license.

Follow-up inspections
Follow-up inspections are inspections performed during the validity of the license after an initial inspection, with the goal of verifying the fulfillment of the operational radiation protection guidelines developed by the users, and the task and controls of the RX supplier company. The points checked on in this inspection are quite similar to the points inspected in an initial inspection.

Audits
An audit is a special inspection and is made up of a general (brief) inspection of the radioprotection process in the company or institution without a detailed check of the installation itself and the radioprotection plans. Audits are regularly undertaken in research institutions or specialized companies where no uniform inspection reports and inspections can be applied.

Table 1: Time schedule for inspection for RX installations for diagnostic and therapy

Firm	Initial inspection	Follow-up inspection/Audit	Administrative inspection
Doctors Dentists Veterinary surgeons Chiropractors	Within the 1st year after issue of license - randomly - always with therapy apparatus	Within the deadline of the licenses (10 years) - as the case may be	Systematically every 3 years or 6 years following the revision of the installation by the installation firm. - as the case may be - if needed
Hospital RX institutes	Within the 1st year after issue of license - always with high doses apparatus (RAD, RD, CT) and by therapy - all others randomly	Within the deadline of the licenses (10 years) - in Hospital usually every two years	Systematically every 3 years or 6 years following the revision of the installation by the installation firm. - as the case may be - if needed
RX trading company	Within the 1st year after issue of license	Annually	Organization of every 2 years by SFOPH of a ½ day seminar
Film trading company	-	-	Organization of every 2 years by SFOPH of a ½ day seminar

Administrative inspections
This survey deals with the gathering of information per telephone, e-mail, fax or letter in order to clarify points as: realization of requirements, license specification, periodical inspection forms delivered by supplier companies, annual reports, custom declarations, special questions on radioprotection issues in selected installations. Depending on the licenses and installations supervised, the administrative inspections for the use of ionizing radiation are different. The time used for this kind of survey is dictated by the received annual reports as well as other reports made by the license holder or other organs. The number of administrative inspections made per year is ascertained by the annual goals and actions decided on by the Radioprotection Division of the SFOPH.

Table 2: Time schedule for inspection for other installations dealing with ionizing radiation

Firm	Initial inspection	Follow-up inspection/Audit	Administrative inspection
Nuclear medicine	Within the 1st year after issue of license - usual	Within the deadline of the license (10 years) - every 3 years	Systematically every years with announcement of the use of nuclides - other individually, as the case may be
Research Labor using unsealed sources (A, B or C Labors [2])	Within the 1st year after issue of license - usual	Within the deadline of the license (10 years) - every 5 years	- as the case may be
Radio-oncology	Within the 1st year after issue of license - usual	Within the deadline of the license (10 years) - every 5 years	- as the case may be
School University Formation center	Within the 1st year after the elaboration of the licenses - usual	Within the deadline of the licenses (10 years) - randomly	- as the case may be
Non medicinal RX installation	Within the 1st year after issue of license - randomly	Within the deadline of the license (10 years) - randomly	- as the case may be
Small sealed sources	Within the 1st year after issue of license - randomly	Within the deadline of the license (10 years) - randomly	- as the case may be
Big sealed sources	Within the 1st year after issue of license - usual	Within the deadline of the license (10 years) - once per year	- Annually, report of the location of every individual sealed sources
Non medicinal accelerators	Within the 1st year after issue of license - usual	Within the deadline of the licenses (10 years) - as the case may be	- as the case may be
Trading company	-	- as the case may be	- as the case may be - annual report

Scope of inspection activities

Initial inspection
An initial inspection of all installations requesting license, which were not previously active in the field of ionization radiation, is systematically undertaken. The procedure is different for organizations which already have experience in this area of activity. For purely administrative licenses (e.g. trade, import/export) there is no initial inspection.

The assessment made is in principle based on requirements laid out in the inspection protocol. In the case of medical units, the elements relevant to the dose are merely checked randomly, since the corresponding values have to be checked by the X-ray manufacturer upon delivery of the unit

The minimum assessment includes:

- Inspection of the item for which the license is requested (for medical installation also random check)
- Inspection of the installation logbook
- Examination of the operational radiation protection
- Thorough inspection of structural (i.e. building) radiation protection aspects

Follow-up inspection

The motive for a follow-up inspection depends on the type of licenses and installation that a company has, and is decided from case to case, or according to annual goals. It will be based on the corresponding inspection protocol.

For diagnostic radiography units, the main points are:

- dose-intensive investigations with CT and interventional radiology
- doubtful installations, or those with low efficiency
- doubtful activity of X-ray machine manufacturer
- doubtful interpretations of guidelines by local experts
- before the renewal of a license

The minimum assessment includes:

- Random check of the licensed installation, in particular of dose related quantities
- Inspection of the installation logbook
- Examination of the operational radiation protection
- Random check inspection of structural (i.e. building) radiation protection aspects

Audit

The decision to conduct an audit depends on the type of authorization – installation. It is decided case by case or according to annual goals, as an alternative to a follow-up inspection.
It is mainly conducted according to the requirements of the corresponding audit protocol and includes the following points:

- Observance of requirements / instructions
- Fulfillment of QA requirements (individual actions and frequency)
- Continuing professional further training (internal / external)

Quality inspection of RX installations in the medical field

Quality control of RX installations in the medical fields are regulated in several ordinances dealing with radioprotection [2, 3]. The SFOPH has delegated a part of its responsibility to the RX supplier company itself. These trading companies are supervised by the SFOPH and own a license for the handling, installation and maintenance of RX apparatus. These companies are also required to have a Quality Assurance Management. With this obligation and the permanent inspections of the firms we can guarantee that the companies have enough competence to undertake a lot of controls. Table 3 gives an overview of who is responsible, who can perform the quality control inspections, and also the periodicity of such inspections.

Enforcement by law and licenses

The SFOPH as the responsible licensing authority and regulatory body, issues licenses to all institutes dealing with installations emitting ionization in the research and medical field. These licenses are official documents which contain a description of the authorized activity including any conditions imposed and requirements. The users are obliged to fulfill usually within a given deadline the mentioned requirements. The non respect of requirements or recommendations can lead to a withdrawal or non issue of a license. The SFOPH makes a great effort to give a lot of advice and takes the opportunity to discuss with the user in order to open a dialogue. The SFOPH uses this possibility as much as possible in order not to play the role of a policeman.

Table 3. Periodicity of the survey by the RX supplier firm, regulatory body and license holder (user).

Rx supplier	License holder (user) (Hospital, etc.)	Regulatory body (SFOPH)	Time schedule periodicity
Installation of the RX	Demand of a licence	Issue of the licence validity 10 years	T_0
Acceptance test			T_0
Delivery of the installation			T_0
	Annual constancy test	Radioprotection control	1st year
	Annual constancy test		2nd year
Maintenance Test			3rd year
	Annual constancy test		4th year
	Annual constancy test		5th year
Maintenance Test		Radioprotection control For periodicity see Table 1	6th year
	Annual constancy test		7th year
	Annual constancy test		8th year
Maintenance Test			9th year
		Licence renewed Validity 10 years	10th year

Dosimetry survey for workers
During an inspection not only the above mentioned points are checked. The SFOPH has also developed tools which allow the control and overview of the dose exposure of the workers and the patients. Here are a few of these tools:

Review of annual dose
In Switzerland the annual doses received by persons working with ionizing radiation is determined for about 65'000 persons. In general in the field of research and medicine 20 values per year are over the 2 mSv value fixed by the law for a survey period of 1 month and 50 values of dose are greater than the threshold of 10 msV for extremity. The most cases involved doctors, who accumulate doses regularly in their daily jobs, especially in interventional radiology. In no case the annual limit of 20 mSv for the whole body and 500 mSv for the extremities was exceeded. All the doses are registered in a central dose registry (ZDR) and all higher doses are announced. In all the case of excess-dose remarked, an inspection is organized or an explanation of the case is demanded and a follow up is started. During an usual inspection a control of the dosimeters is systematically made and the received doses are analyzed and the procedures involving radioprotection issues are discussed with the user.

External radiation doses were measured using dosimeters worn by occupationally exposed persons. The types of dosimeters used are TLD dosimeters, DIS dosimeters and films. In principle, the personal dose equivalent Hp (10) was estimated. The contribution of natural radiation was always subtracted. The doses were reported to the contractor, the central dose registry (ZDR) and the Swiss Federal Nuclear Safety Inspectorate, if the people work in that field. When necessary, special neutron dosimeters are also used. Occasionally, instead of using personal neutron dosimeters, the ambient neutron dose was measured. In that case, neutron doses were calculated based on the person's exposure time. Two of the 4948 people monitored had received a neutron dose exceeding 1 mSv (2.4 mSv and 3.7 mSv). The neutron doses are included in the data for Hp(10). The personal dose equivalents from external radiation are given in table 4, with the number of persons and the collective dose. In 2003, the number of persons occupationally exposed to ionizing radiation was 65'345, which is slightly higher than the figure of 64'487 for 2002. The collective dose, i.e. the sum of the personal

doses of all persons occupationally exposed to ionizing radiation in Switzerland was 4.81 person-Sv in 2003 [4], as compared with 4.45 person-Sv in the previous year. This slight increase in dose is mainly due of the increase in collective dose in the research sector. The contributions of different sectors to the collective dose were: nuclear power stations 63 %, medicine 18 %, research 15 %, industry, trade, public sector and miscellaneous 4 %. The reported dose of workers (see table 4) gives a trend and is used to define the number of inspections undertaken by the Radioprotection Division of the SFOPH.

Table 4: Personal dose equivalent from external radiation exposure in 2003: Number of persons and collective doses [3].

Dose interval (*) [mSv]	Hos-pitals	Medical practices	Radio-logical Medical practices	Dental practices	Univer-sities research	Nuclear power stations	Industry, trade	Public sector	Miscel-laneous	Total
0 – 1	17561	16815	397	13366	8526	2656	2142	419	2238	64120
1 – 2	64	9	3	5	91	387	16		3	578
2 – 3	21	4	2	1	25	203	9			265
3 – 4	13	1	0		18	123	5			160
4 – 5	7		1		9	59	6			82
5 – 6	6		0		0	34	3			43
6 – 7	4		1		4	21	3			33
7 – 8	6		1		1	16	1			25
8 – 9	1				2	15	0			18
9 -10	1					6	0			7
10-11	0					5	1			6
11-12	1					3				4
12-13	1					2				3
13-14						1				1
14-15										
15-16										
16-17										
17-18										
18-19										
19-20										
20 – 50										
> 50,0										
Total	17686	16829	405	13372	8676	3531	2186	419	2241	65345
Collective dose [person-Sv]	0.56	0.10	0.04	0.17	0.72	3.02	0.18	0.00	0.02	4.81

Note: If a person has been active in several sectors, the data are allocated to the sector that contributes the most to the dose; if there are equal contributions from more than one sector, the data are allocated to the sector with the longest occupational involvement.
(*) Doses that fall exactly on the boundary between intervals are allocated to the lower interval.

Sorting measurement (triage)

The SFOPH has published a directive about sorting measurements if an institute works with unsealed radioactive substances. This directive is the implementation of a new dosimetry ordinance which was introduced in 2000. This directive is also a means of control. This directive was introduced, because the follow up of external dosimetry had shown, that volatile nuclide and other form of substances can not be detected with normal dosimetry. It described the kind of measurement (urine analysis, thyroid measurement, dose rate measurement, etc.) which is suitable to detect the incorporation of nuclide by the workers. It also defined the minimal requirement on the measurement device in order to be able to see the threshold and the limit fixed by the ordinance. The SFOPH usually checks these sorting measurements during laboratory inspections.

Intercomparison controls

Measurements of personal doses are carried out in Switzerland by 10 dosimetry services. Each dosimeter service is approved for a given method and nuclide for the measurement of doses. Article 50 of the Radiation Protection Ordinance [1] requires comparison exercises within dosimeter services. The SFOPH organized each year as survey a comparison in collaboration with a specialized

company. The last comparison exercise was carried out in 2003 by the Paul Scherrer Institute. In addition to the normal control at the reference point, using Cs-137, the measurement accuracy of dosimeters to measure the irradiation of extremities was also investigated. One dosimeter service did not fulfill the requirements for Cs-137 radiation using a whole body dosimeter under reference conditions. This dosimeter service is currently acquiring a new dosimeter system. The new approval procedure will check whether the requirements are met. The requirements concerning measurements using extremity dosimeters for Cs-137 radiation were broadly satisfied and the supervisory authorities did not require that any particular measures be taken in this area. The 34th comparison exercise involved measurements of iodine incorporation in the thyroid, and it was prepared and carried out by the University Institute of Applied Radiation Physics (IRA). Apart from the IRA, only two other dosimeter services have been approved for iodine measurements. One of these services did not fulfill the requirements of the Dosimeter Ordinance. In that case, the approval authority has ordered a recalibration of the service.

Diagnostic reference levels

The application of the ALARA principle by the regulatory body for patients in the medical field is quite different. There exist no limits of dose for patients in the medical field and especially in radio diagnostics. The application of the two other principles of the Swiss law, the optimization and justification should guarantee sufficient protection for the patient. The International Commission on Radiological Protection (ICRP) introduced the term “DRL” for the first time in 1996 [5]. The Commission specifies that it is advisory to define reference values to dose applied to patients or resulting from the intake of radiopharmaceutical. The Commission also calls for a local review if the reference values consistently exceeded the international DRL. It is recommended to use easily measurable quantities to establish DRLs, such as entrance surface dose and dose-area product, etc. DRLs are designed to complete the technical appreciation, but do not constitute a limit between a good and bad practice.

The SFOPH has just published a note about radiography *(Note R-08-04, Diagnostic Reference Level (DRL) for radiographic examinations*, available on www.str-rad.ch), in which the European DRL are listed. This note describes in detail the determination of dosimeter quantities relevant to practical radiology. In addition, the SFOPH has made a program available on its website, which provides the dose calculation and the comparison with the corresponding DRL, as well as records the resulting information in a data base.

In Switzerland in early 2000 the SFOPH set up with the collaboration of the University Institute of Applied Radiation Physics (IRA) a working group on the optimization of radiation protection in the case of dose-intensive X-ray examinations (Optimierung des Strahlenschutzes bei dosisintensiven Untersuchungen in der Radiologie – OSUR). Several medical associations concerned by the issue were invited to take part in this working group: general practitioners, radiologists, cardiologists, radiographers, medical physicists. One of the main issues addressed by the working group relates to diagnostic reference levels (DRLs), whose definition, establishment and implementation have become of central importance in recent years in the management of radiation doses delivered to the patient in diagnostic and interventional radiology.

The above mentioned DRL can play a useful role in the field of high dose examinations and might help towards improvements. In order to optimize high dose examination in interventional radiology, specific practices were selected on the basis of a detailed questionnaire. All the radiological departments taking part in the study have been equipped with a surface-dose measuring instrument by the SFOPH, calibrated by IRA and checked for image quality. The results of the survey [6] completed in June 2003 are now available and a detailed report has been submitted to relevant organizations. Once these have drafted their comments, a final report will be published.

Within the framework of the DRL determination project, a cooperation contract was agreed between the SFOPH and the Radiological Physics Division at the Basel Cantonal Hospital. The aim of this cooperation is to draw up a survey of doses delivered to patients from nuclear medicine investigations techniques. It includes the following tasks: survey, data processing, determination of reference levels for diagnostic investigations, transmission of data to interested parties, publications of results and conclusions, as well as organization of continuing professional development. This is done in collaboration with several Swiss professional associations (the Swiss Society of Nuclear Medicine, Swiss Society of Radiopharmacy / Radiopharmaceutical Chemistry and the Swiss Association of medical radiology technicians). The deadline for the completion of this study is end of 2004.

The investigation into high doses examinations in cardiology has already been completed in the French-speaking part Switzerland and is underway in the German-speaking part of Switzerland. Preliminary results are expected for the beginning of 2004. Eight clinics in Switzerland took part in a European study on CT, with a detailed protocol defined for 114 CT investigations. Results so far show no significant difference between the European DRL and those derived from the study for adults. However, the Swiss values for pediatric investigations are markedly lower than the corresponding European ones. The evaluation is still in progress and the full results will be published by the SFOPH in 2004.

These local reviews, reports and directives as well as the introduction of these DRL by the Radioprotection Division of the SFOPH will certainly improve and optimize the dose received by patients. The introduction of these DRL is in an early stage and the improvement and reduction of the dose for several examination and treatments in the medical field will certainly be observed in a near future.

Protection in Radiology

Different perceptions amongst professionals on the necessity/usefulness/legitimacy for staff and the public to use protection (lead apron) for diagnostic examinations have necessitated the SFOPH to put forth a recommendation aiming at standardizing practices. This document was then forwarded to the Federal Commission for Radiation Protection and Surveillance of Radioactivity (CPR) for consultation, the outcome has been included in a note on protections required for radiological investigations (for patients, staff and the public) (Note R-09-02 Schutzmittel für Patienten/Personal/Dritte available on www.str-rad.ch).

Thanks

I would like to thank my SFOPH colleagues for their precious help in gathering all the data for this paper.

References

[1] Swiss Legislation on radiological Protection, 814.50, 22 June 1991.
[2] Radiological Protection Ordinance, 22 June 1994.
[3] RX ordinance, 20 January 1998.
[4] Annual Report 2003, Dosimetry of persons occupationally exposed to ionizing radiation in Switzerland, mars 2004.
[5] International Commission on Radiological Protection (ICRP). Avoidance of Radiation Injuries from Medical Interventional Procedures. Publication 85. 2000.
[6] Diagnostic Reference Levels (DRL) for Diagnostic and Interventional Radiology: the Swiss Situation. Aroua A, Besançon A, Buchillier-Decka I, Trueb P, Valley JF, Verdun FR and Zeller W. in press (2003).