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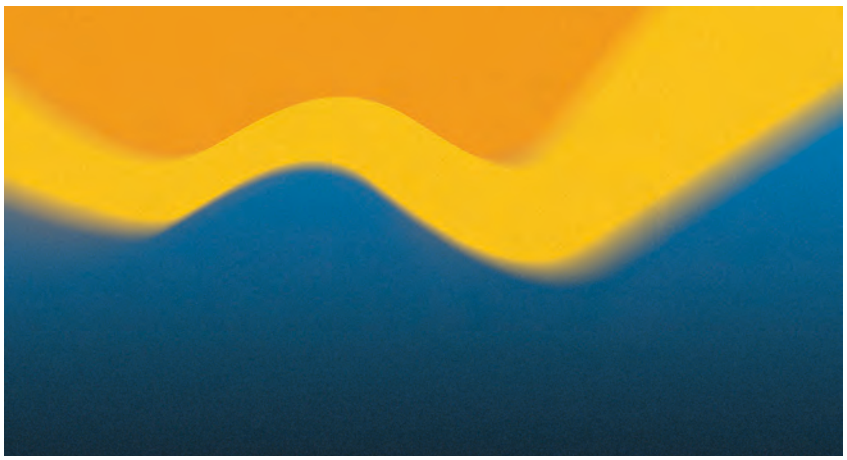
Division of Radiological Protection



Final Report
Supervisory activities in the operation theatres of Swiss Hospitals
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Supervisory activities in the operating theatres of Swiss Hospitals

Final Report

Abstract/Summary

In 2018, the Radiotherapy and Medical Diagnostics Section of the Radiological Protection Division of the Federal Office of Public Health FOPH[1] concluded its supervisory activity that focused on the operating theatres of Swiss hospitals.
A total of 207 operating theatre inspections were carried out in the period between 2015 and 2019. All operating theatres of Swiss hospitals were therefore inspected at least once.

The radiological inspections consisted of a practical part in the operating theatre and a subsequent administrative discussion. In the practical part, the handling of the X-ray device by the staff in the operating theatre was observed and assessed. In the administrative discussion, compliance with the requirements of the radiological protection legislation was checked

Following the inspection, each hospital received a written report. Measures resulting from the inspection had to be implemented within the agreed deadlines and reported to the FOPH. All hospitals had to regulate their organisation of radiation protection in the operating theatre area using organisational charts and internal instructions.

The major findings of the practical and administrative inspections are summarised under key topics in the graphical representation (on page 2). It becomes apparent that there is an urgent need for action and optimisation in terms of radiation protection in operating theatres of Swiss hospitals, especially in the radiation protection organisation, training and education, personal dosimetry, protective equipment and use of the technology.

The FOPH will closely monitor the feedback from the hospitals with regards to the revisions of the measures. Moreover, inspections will be repeated: principally in hospitals with particularly serious deficiencies, as well as in some hospitals in the form of spot-checks.
The relevant medical professional societies will be informed of the deficiencies and will be asked for their opinion, together with proposals to improve the situation.
The FOPH is drawing up guidelines in which "best practice" standards are summarised. These provide advice to the operating theatre staff and to those responsible for technical radiological protection, supporting them in their day-to-day work.

1 All abbreviations in the Table may be found at the end of the report.

This approach involving interdisciplinary collaboration aims to bring about an improved culture of radiological protection.

The use of modern imaging techniques (CT and CBCT) in the operating theatre and the increasing number of hybrid operating theatres will also bring further challenges.

Key topics

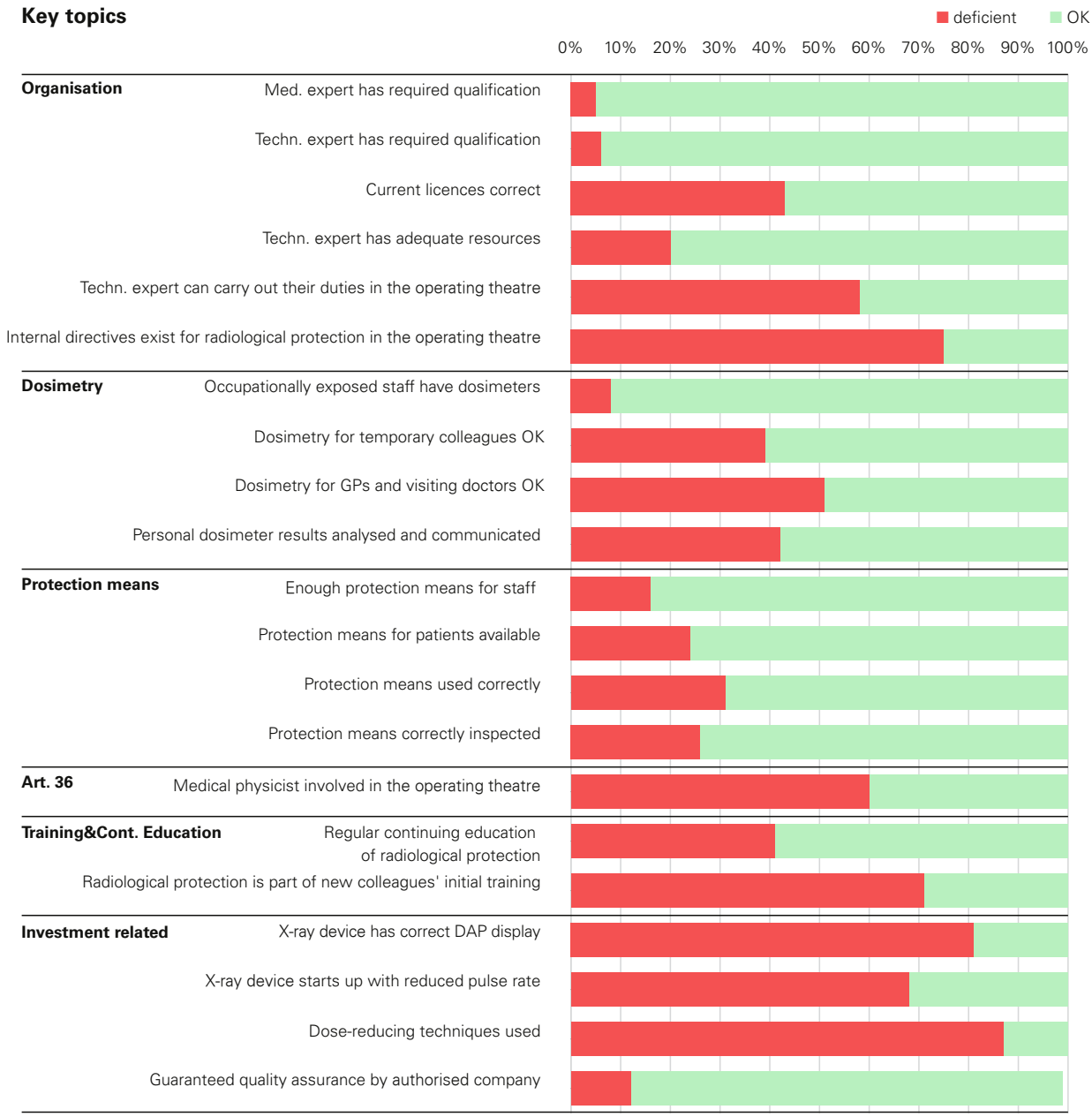


Diagram 1: Operating theatre inspection results (key issues) and assessment by the FOPH

Introduction

Anyone who regularly deals with ionising radiation in the course of their professional activity is deemed to be occupationally exposed to radiation. Therefore, in Switzerland, they must be registered with a recognised personal dosimetry laboratory, wear their personal dosimeter at work and, depending on their function, wear suitable protective clothing. Of the almost 100 000 people who are occupationally exposed to radiation in Switzerland, about one third works in hospitals. They are active as nursing staff in *inter alia*

- emergency units
- endoscopy/gastroenterology
- urology
- cardiology
- operation theatres

The largest proportion of nursing staff works in the operating theatres. Their knowledge of radiological protection varies greatly - according to the different professional groups and their training. At present, no recognised training in radiological protection exists for such workers.
Unlike radiology staff, the operating theatre one cannot leave their workstation during procedures involving radiation. Consequently, in addition to the surgeon, there are always several people exposed in the operating theatre.

The FOPH inspections were intended to survey and analyse the radiological protection situation in the operating theatres of Swiss hospitals. Key points of the inspections were the organisation and implementation of the radiological protection, interdisciplinary communication and practical working techniques. Further objectives were to raise awareness of the operating theatre staff and to monitor compliance with the legal radiological protection regulations.
In addition, the inspections made it possible to inform the operating theatre staff about the requirements of the revised ordinances on radiation protection.

Figure 2: In the operating theatre, many different occupational groups are exposed to ionising radiation in addition to the surgeon.

Inspected Hospitals

A total of 198 hospitals were inspected. Each operating theatre was inspected at least once. In large hospital centres and university hospitals, a number of inspections were carried out in the various specialised departments.
The major focus of the inspection related to the use of mobile fluoroscopy X-ray devices in the operating theatres.
Hospitals that carried out solely small interventions, including cardiology and angiology departments and radiology departments, did not fall into the group targeted for priority inspections.

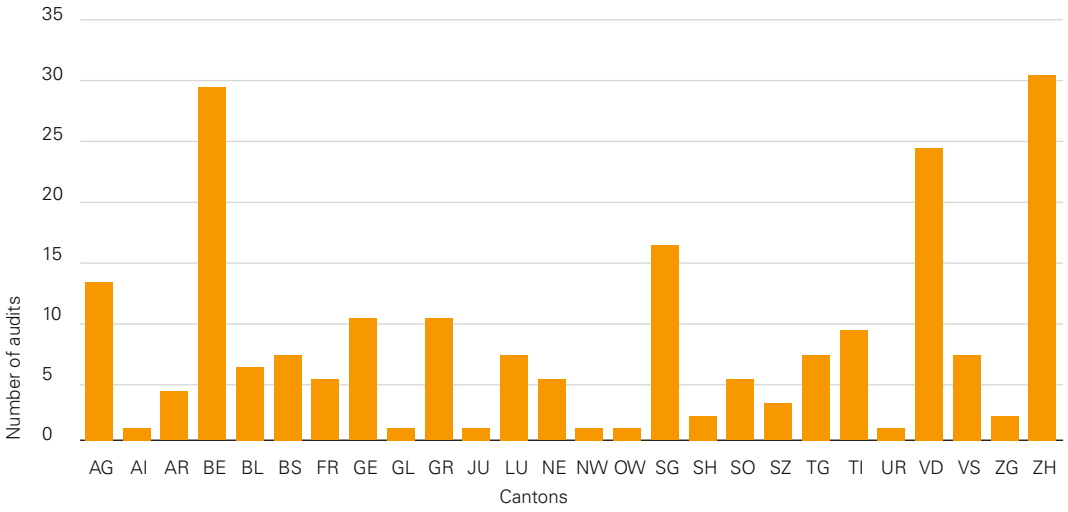


Diagram 3: Number of inspections carried out in 198 hospitals across all Swiss cantons

Inspection planning

The operating theatre inspections initially started by contacting the persons who were designated as the experts for technical radiological protection in the licences to operate X-ray devices. These people usually work in radiology departments. The FOPH requested that an operating theatre would be reserved for the operating theatre inspection, that an interdisciplinary operating theatre team would be set up and that suitable appointment dates could be proposed. In almost all cases, the request was either directly forwarded to the staff in the operating theatre or a person responsible for the operating theatre was nominated as the contact person to handle further planning.

The supervisory activity of the FOPH for radiological protection in the operating theatre – in contrast to the radiology departments - was scarcely or not known at all up to then. This was one of several factors, which in some cases led to a very long preparation phase prior to the inspection.
The duration between the initial contact with the responsible expert(s) and the actual inspection date was of 1.2 to 13.5 months. In some cases, as a result of uncertainties with regards to internal responsibilities in the hospitals, there were serious delays in arranging appointments for the inspections.

Carrying out the inspections

Inspections in the operating theatres were planned, prepared and completed in collaboration with the inspected hospitals. These were informed in writing of the operating theatre inspection procedure. A complete operating theatre inspection consisted of a practical and an administrative part.
An operating theatre was reserved for the practical part. An operation was simulated in the operating theatre with a team of physicians and non-medical operating theatre staff. A phantom served as the "patient". The operating theatre team could operate in their usual working environment and use their usual infrastructure. Ideas for modifying work processes and proposals for improvement could therefore be tested immediately.
During or immediately after the practical part of the inspection, the conformity of the constructed structural shielding to the calculated shielding was checked.
The administrative part of the inspection included a discussion of the organisation chart of the radiological protection staff in the hospital. Other topics were the perception of radiological protection tasks, personal dosimetry, regular training updates on radiological protection and quality assurance of the X-ray equipment.
The complete inspection was estimated to take three to four hours.

The operating theatre inspections were carried out in the form of group interviews. The FOPH inspection team usually included two people: a supervisor responsible for the canton, and a specialist with many years of professional experience in the field of nursing and operating theatres. The former checked compliance with the legal radiological protection regulations and explained and defined, in consultation with the hospitals, the measures required to ensure a legally compliant operation. The specialist was responsible for carrying out the practical part of the inspection using a standardised procedure adapted to the state of knowledge of the acting operating theatre team. The specialist supported the administrative part of the inspection, and was available to the operating theatre team – even after the inspection – for questions on the organisation of radiological protection, for drawing up organisation charts and as a contact person for internal communications. Following the inspection, the cantonal representative summarized the findings in a report and sent it to the hospital. The measures described in the report had to be implemented by a defined deadline and notified to the FOPH.

A total of 1,723 persons participated in solely the practical procedures of the operating theatre inspections. The number of participants per inspection varied between 2 and 28 people (median: 8 participants).
The participants could be assigned to the following professional groups:

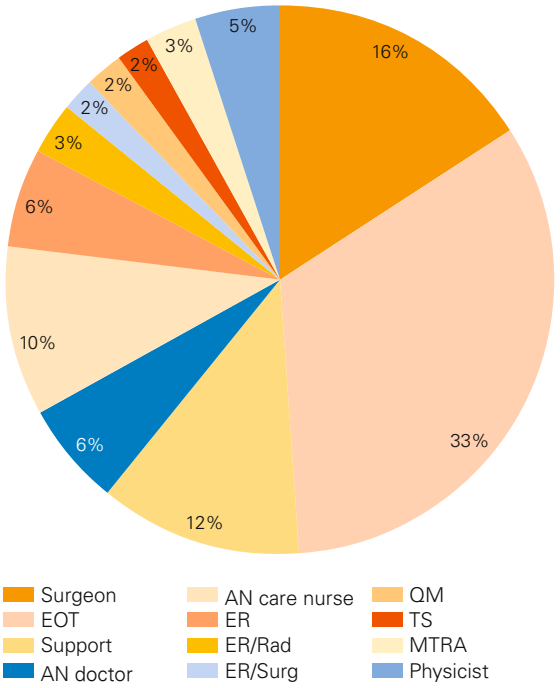


Diagram 4: Inspection participants according to professional groups (abbreviations can be found at the end of the report).

Procedures for the practical inspections

Each practical part of the inspection began in the reserved operating theatre. The FOPH inspection team shortly presented its tasks and supervisory function. Attention was then drawn to the "patient", a water phantom. Because of its similarities to a human torso (volume, composition), the staff were exposed during the simulation to a level of radiation comparable to the one received during a real operation.

The invisible X-rays were "rendered visible" to the staff by means of a real-time dosimetry system (Unfors Raysafe i2). During an inspection, the cumulative X-ray fluoroscopy times generally not exceeded 30 seconds. The participants were informed accordingly and they also had the possibility to leave the room during the exposure. Then the FOPH team informed about the different types of radiation that are generated: primary radiation generated by the equipment and used for imaging. Scattered radiation generated as a by-product when the primary radiation interacts with the object under investigation.
Above all, the scattered radiation emitted from the patient causes the occupational exposure of the operating theatre staff. Its quantity depends on the thickness, the density and the material of the irradiated volume: when imaging a lower leg, there is less scattered radiation than when imaging the spine or pelvis.
People with special tasks in the operating theatre team were chosen from the participants in the hospital inspection: operator and assistant, staff in charge of instruments, C-arm operators, anaesthesiologists and when possible an assistant. In addition to their personal dosimeter, each person was equipped with a real-time dosimeter (vide supra) over their protective clothing.

Positioning the operating theatre team

The C-arm was set up and positioned similar to a real intervention. The persons took on their assigned position for an intervention. Operators and assistants stood close to the table. The anaesthetist was at the head of the table, the C-arm operator was behind or beside the C-arm. The assistants were placed where needed and therefore did not have a fixed position.

During the inspection, the operators indicated that they most frequently used the C-arm in an under-table mode or in a horizontal beam direction. The above-table mode is rarely or never used. However, the x-ray tube's over-table position is standard in urology and mini C-arm design, to the astonishment of most users.
The radiation exposure of the staff was dependent on their position with respect to the radiation source (patient). In many interventions, C-arm operators and anaesthetists had a favourable position from the point of view of radiological protection. C-arm operators were often protected by the C-arm, anaesthetists were protected in the case of permanently installed operating theatre tables by the massive table leg.
In general, during the intervention, the operators and assistants, who remained at their position at the table, were subjected to the highest exposure. Therefore, it was most important for them to become aware of the typical direction of divergence of the scattered radiation. Only in this way could they – as far as possible – optimise their position and exposure during fluoroscopy.
The horizontal beam direction is used *inter alia* in spinal surgery and pain therapy. The scattered radiation diverges from the patient towards the X-ray tube, where at least one operator usually works. These persons have to be adequately protected since they cannot leave their position during fluoroscopy.

In surgery of the extremities, significant exposures of the staff were also observed in the inspections. Mini-C-arms are frequently used in such interventions. Due to their design, these devices have to work in the above-table mode. Operators therefore have the advantage that they can place the object to be imaged directly on the image intensifier or detector. The operators are generally in a sitting position and consequently closer to the scattered radiation than when standing. The face, in particular the crystalline lenses of the eyes, and the thyroid are considered in such situations as organs at risk when exposed. Consequently, adequate means of protection should also be used for these organs.

Technical adjustments of the C-arm

The technical adjustments of the C-arm also influenced the exposure of all participants. The settings used to start up the C-arm could be stored as standard settings. Generally, the standard program corresponded to the one being mostly used. The fluoroscopic program was chosen more for reasons of image quality than for considerations of radiological protection.
In the operating theatre inspections, the relevant standard setting parameters (kV, mA, pulse rate) were recorded and documented. The pre-set kV values were between 40 and 90 kV after start up.

The use of a lower pulse rate and collimation can reduce the exposure of the operating theatre staff by 50-80%.

In order to ensure a constant image quality, the system automatically controls the tube voltage and tube current during fluoroscopy.

Pulsed fluoroscopy and pulse rate

The pulse rate can likewise be pre-set. The higher it is, the better the movements can be observed. However, the greater the exposure of the patient and staff will be. In more than 70% of cases the pulse rate was set so high (more than 25 pulses per second) that it was comparable with continuous fluoroscopy.

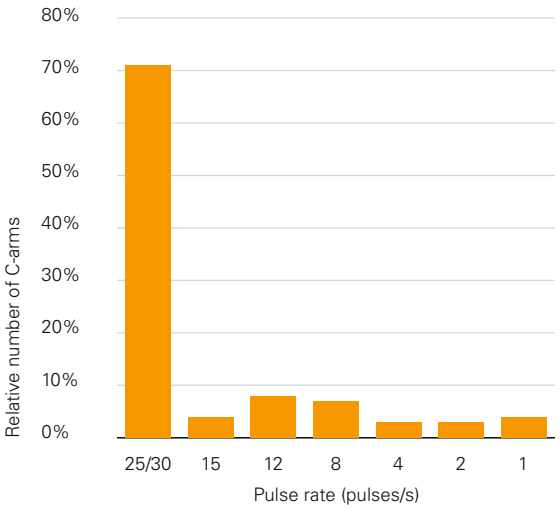


Diagram 5: Pre-set pulse rates

Collimation

Collimation at the area of interest is another method to reduce scattered radiation. Here, either lateral or circular collimators are brought into the beam path, limiting the radiation field and thus indirectly the divergence of the scattered radiation.

In addition, collimation improves the image quality because less scattered radiation is generated. This technology was used by only 33% of hospitals. It has to be noted that the correct application of the collimators was strongly dependent on the operator.

In summary: In 39% of hospitals, the staff had noticeably little understanding of dose-reducing techniques. The remaining 61% of hospitals were aware of these techniques. However, existing knowledge does not guarantee its application in routine operations. Accordingly, these optimisation techniques were seldom or never applied in more than 68% of hospitals.

Metal button

Modern C-arm systems have a "metal button" on the control panel. When activated, the image quality (and therefore the intensity of the effective radiation) is determined not by the already implanted metal, but rather by the less dense tissue. Thus, the overall image quality can be improved and the radiological exposure of the patient and staff reduced.

DAP display according to the X-ray Ordinance

X-ray systems for use in the medium and high-dose range (effective patient dose >1mSv) must have a DAP display. Article 22 of the revised X-ray Ordinance requires mGy cm2 (Gy cm2 in interventional radiology) as the display unit.

The DAP displayed on the monitor can inform the user of the applied radiation dose. Moreover, the DAP is required for the dose documentation and the comparison with the diagnostic reference values.

In 81% of the equipment used in the inspections the DAP was not displayed with the correct unit.

Means of protection and their inspection

The X-ray units in operating theatres are generally mobile and applicable in various beam directions. Means of protection for staff were an important topic in all hospitals.

Many participants – irrespective of their particular professional background – were not aware that the means of protection had to be strictly worn correctly. Very often, it was believed that aprons, protective means ending above the knee or a simple skirt were sufficient.

In the supervised area it is mandatory to wear protective equipment and a personal dosimeter underneath.

Operating theatre teams stated that the budgets for new protective means were always limited or had to be fought for, as the existing means of protection were believed to be adequate by the licence holder. It was striking that the advice and support by protective equipment distributors led neither to better equipment, which complied with the provisions of the X-ray Ordinance, nor to a customised selection of protective equipment for the operating theatre.

In more than 45 hospitals, the equipment of protection means was inadequate. The shortcomings ranged from poor quality to insufficient quantity, or to ill-fitting protective equipment.

The correct utilisation of protective equipment for the operating theatre team requires that the individual working position must also be taken into account. Thus, those who work close to the table should wear a thyroid protector with at least a 0.5 mm lead equivalent. This protective measure is optional for the other operating theatre team members.

The use of lead gloves was rarely observed in the inspections. When used, they were clearly always used incorrectly: The gloves were worn for work in the primary beam. Due to the automatic exposure control of the X-ray unit, this led to an increased radiation exposure of all participants.

For patients, the gonads were regularly named as body regions which needed to be protected. The purpose of the inspections is to promote understanding of a more comprehensive, intervention-based application of protection. It has to be noted that personal protection equipment is not very suitable for being used for patients. Therefore, concepts for the reasonable use of patient protection products had to be created. In some hospitals, there were no protection means for patients, while in others only one-sided lead mats were available. Consequently, patients could not be adequately protected from unnecessary exposures; patient protection products should be usable as circulatory wrap-around protection. Thus, a quarter of the hospitals had to acquire means of protection for patients.

Means of protection can only be fully effective if they are intact. Therefore, they must be tested for integrity and operability. These checks were not carried out in more than 17% of hospitals.

The examination of staff and patient protection products by means of a C-arm leads to an inadmissible exposure of the staff. Alternative techniques are CT or stationary fluoroscopic units, which can be operated from a control room.

The FOPH recommends to inspect all newly acquired protection equipment before use in order to identify any possible deficiencies from the beginning.

Personal dosimetry

All persons who are occupationally exposed to radiation must wear a personal dosimeter in order to determine their exposure. Deficient information and inadequate communication on personal dosimetry led to misbehaviour. Some of the staff occupationally exposed to radiation worried about disconcerting consequences in case the measured value differed from 0 mSv. Others doubted whether the monthly doses regularly stated to be 0 mSv were realistic.

Both of these concerns led to a lack of moral commitment to wear a personal dosimeter. The dosimeter must be consistently worn in order for the actual exposure to be measured realistically.

In the FOPH inspections, details were requested on the implementation of personal dosimetry. Information was very inadequate or unavailable in just under 8% of the cases. Staff who were occupationally exposed to radiation were unidentified as such or whole groups of staff were not included in the definition. The inspections showed that general practitioners and visiting physicians as well as temporary staff or trainees were not subject to dosimetry in about half of the hospitals. They did not always follow the usual personnel procedures because their recruitment procedures were managed differently from those of the permanent staff. In principle, temporary employees were more likely to wear a dosimeter than general practitioners and visiting physicians.

In about 50% of hospitals dosimetry was not organised for general practitioners and visiting physicians.

Dose-intensive interventions were regularly or very often performed in more than 50% of the inspected hospitals. In such examinations, if the occupational radiation exposure cannot be reliably determined by means of a single dosimeter, a second dosimeter above the apron or extremity or eye lens dosimeters have to be worn in addition to the personal dosimeter. In the operating theatre, this concerns *inter alia* urology, neurosurgery, vascular surgery and pain therapy.

Less than 4% of the hospitals had implemented a double dosimetry in the operating theatre – and this only to estimate exposure to the eye lens.

Wearing only a dosimeter is not sufficient. The dosimetry procedure also includes the analysis of the evaluation data, the regular communication of the personal doses to the staff members and optionally further measures (clarification of increased

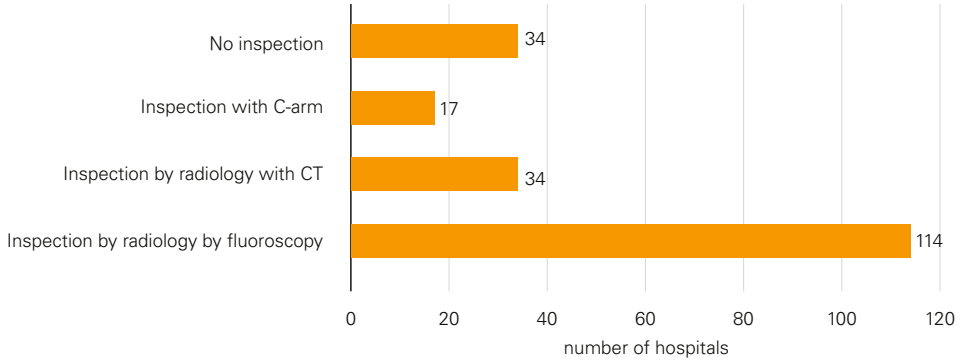


Diagram 6: Inspection of protection equipment; 199 evaluable inspection reports

personal doses, optimisation of protective equipment). In almost all hospitals, the staff who were occupationally exposed to radiation could obtain information on request about their personal dose level values. However, only 60% of hospitals regularly informed their staff on their own initiative.

Dealing with pregnant staff members in the operating theatre

During their pregnancy, female staff members may also work with X-rays. Some women have a great interest in doing this (e.g. female physicians during their specialist training, which requires the completion of a certain catalogue of interventions). Throughout the whole pregnancy, the unborn child must not receive more than a 1 mSv of effective dose.

According to statements from care and technical staff, pregnant employees demanded that they should not work where X-rays were used.

Women who continue to work in the operating theatre, if pregnant, have to wear their dosimeter at stomach level during all working hours. Some hospitals provided their pregnant female staff with an additional electronic dosimeter that showed the accumulated dose in real time. This is the only way to rapidly detect unintentional exposures.

Dose documentation

In the medium and high-dose ranges, exposure parameters have to be documented in such a way that the patient dose can be estimated. In almost 25% of the operating theatres, no exposure parameters were recorded. However, modern devices automatically generate a dose report at the end of the application. When linked to a PACS (Picture Archiving and Communication System) in the radiology department, it can therefore be transmitted and archived in the patient data.

When exposure parameters were documented, very different processes were used:

Manual documentation involves risks: Not all handwriting is legible to everyone. The DAP values from different C-arms are often displayed in different units, such that the sole documentation of the numerical value is insufficient. In addition, there is the danger of numbers being mixed up which cannot be reconstructed later.

The documented or archived doses in the memory of the C-arm are only valid for a transitional period. As soon as the capacity of the internal memory reaches its maximum, the oldest data entries are automatically deleted without warning. Consequently, the permanent storage of data is not possible. The users were unaware of this fact.

Medical physicists in operating theatres

Since 2008, the licence holders for fluoroscopy have to periodically call a medical physicist with an SSRMP-recognised certification. With the revision of the radiological protection ordinances, the basis for their involvement is required for medium and higher dose ranges. In less than 40% of hospitals, a medical physicist was already working in the operating theatre, whereby own medical physicists accounted for a significant number within clinical groups and university hospitals.

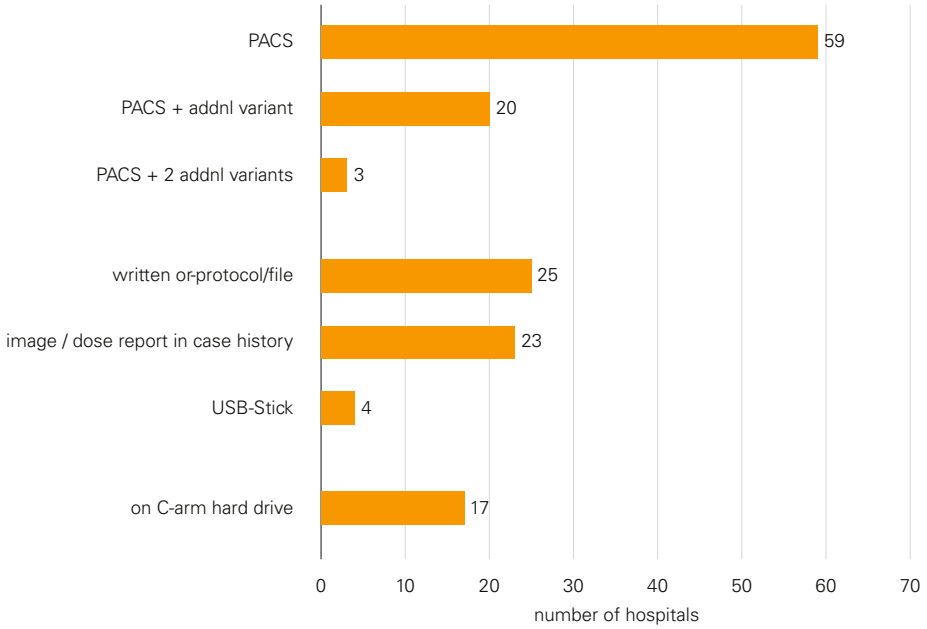


Diagram 7: Dose documentation; 151 analysable inspection reports

2 cf FDHA Ordinance on Radiological Protection for Medical X-ray Systems (XrO) of 26 April 2017 (status on 1 January 2018); SR: 814.542.1: Article 20.

Some medical physicists attended the operating theatre inspections in the hospitals where they were already usually working. Other medical physicists were granted access to the operating theatre only because of the realisation of the inspections. This enabled them to get an idea of the radiation protection knowledge of the operating theatre staff, the typical applications and the working procedures. From this, they were able to deduce how to advise the hospitals on radiation protection issues, how to optimise technical parameters for exposures, how to support operating theatre staff, and how to organise further education courses tailored to the target group.

Implementation of the administrative inspection

Structural radiological protection

The structural radiological protection in the operating theatre was checked before leaving the site. The radiological protection plan that must be submitted to the FOPH as part of the application procedure was compared with the actual situation on site.

In just under a quarter of the hospitals, the shielding calculation does not reflect the actual situation. Not all of the existing windows and doors were marked in the radiological protection plan and/or listed in the calculation table. Normal glass windows were wrongly declared in the plan as lead-glass windows. Supposed steel doors were made of wood.

Additional shielding was correctly labelled in only 50% of the cases.

In one third of the inspections, it was observed that supervised areas were not marked with the radiation warning symbol. In some hospitals, equipment was operated in rooms that were not authorised for the use of ionising radiation.

Checks of all licences issued for the operating theatre of the hospital

The licence situation was discussed with the technical experts: Was all the authorised equipment still operational? Were all operated X-ray devices authorised? Were each of the authorised X-ray devices assigned to the needed treatment areas? Were the X-ray devices that were used for interventions appropriately declared? Were the staff correctly assigned to the machines with the required training for the use of ionising radiation on humans or for the technical radiological protection?

The licences were consistent with the actual situation in only two thirds of the hospitals. The conditions differed in more than 50 hospitals and licenses had to be adjusted.

After the inspection, many hospitals agreed to standardise the licences so that all C-arms could be operated in all authorised operating theatres. In some cases, functional rooms (plaster room, endoscopy rooms) were also taken into account. This allows the users to replace an X-ray system with another if a malfunction occurs.

Organisation of radiological protection responsibility in the hospital

According to Article 16 of the Radiological Protection Act RPA "The licence holder or the persons managing an operation {...} are responsible for compliance with the radiological protection regulations. For this purpose they have to deploy a suitable number of experts and equip them with the required skills and equipment."[3] At least one person qualified to use ionising radiation on humans and a person responsible for technical radiological protection have to be designated for each X-ray device and licence.

The persons responsible for the technical radiological protection can have different professional backgrounds. Many of their tasks are summarised in a FOPH Guideline. They may delegate tasks – but not, however, the responsibility – to persons employed on-site in the operating theatre.

In the course of the inspections, checks were conducted concerning the qualifications of the persons who were designated licence experts for the use of ionising radiation on humans and/or who were responsible for the technical radiological protection. Nine experts responsible for the use of ionising radiation on humans and 13 experts who were responsible for the technical radiological protection did not have the required qualification. In several cases they had already left the hospital. Their leaving had not been notified to the FOPH and furthermore, no replacement had been nominated.

In the course of the inspections, it was found that just under 75% of the experts assigned for the technical radiological protection also received the required competencies to issue directives and resources (work materials, time allocation) along with their nomination/mission. This means that about 25% were indeed designated as the responsible person but could not adequately fulfil their tasks.

Some 40% of the technical radiological protection experts took part in tasks only in areas outside the operating theatre. Therefore, this would imply the assumption that the responsibilities in these operating theatres were defined only on paper but the tasks were not fulfilled.

3 Radiological Protection Act of 22 March 1991 (Status on 1 May 2017); SR: 814.50: Article 16.

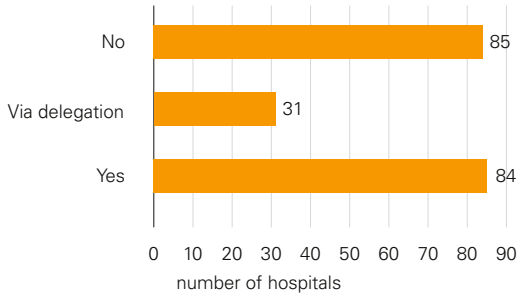


Diagram 8: Technical experts in operating theatres: 200 analysable inspection reports

Organisation chart of internal directives and radiological protection

According to Article 19 paragraph 2 of the Radiological Protection Act RPA "[The licence holder] must moreover:

a. issue internal directives concerning working methods and protective measures and monitor compliance;
b. specify in writing the powers of the various line managers and radiological protection experts, and of persons handling radiation sources."[4]

In this sense, the operating theatre inspections asked about the existence of an internal directive and a radiation protection organization chart. Practically none of the 198 inspected hospitals had an internal directive that explicitly referred to radiological protection in the operating theatre. Some hospitals had directives that generally reproduced the legal regulations. Some directives were present on the internet as SOPs and referred to radiology, medical physics or quality management – but not to the operating theatre. Each hospital had to create an internal directive and submit it to the FOPH for review.

Organisational charts were also rarely available. Logically, the tasks in the organisation chart would have to agree with the tasks in the FOPH-licences. In spite of this, many hospitals found it difficult to create a correct organisational chart. In hospitals with predominantly German employees, specific terms as defined in German legislation were used instead of those as defined in Swiss legislation. This is confusing because in Germany the associated tasks, responsibilities and accountability are differently regulated.

A good internal directive for the operating theatre should provide the newly hired employees with an overview of radiological protection responsibilities in the hospital and practices of everyday radiological protection.
The licence holder is legally obliged to issue directives and monitor compliance. Therefore, the internal directive should be integrated into the quality management system of the hospital and put into effect by the management or the executive board.

Training and continuing education in radiological protection

When starting to work in the operating theatre, employees are generally introduced to their area of responsibility using an in-house radiation protection concept. Staff of an operating theatre have acquired knowledge in radiation protection to a very different extent . Their education in radiological protection was often provided in only a few hours in their occupational training.
Whereas trained personnel in surgical techniques, qualified nurses with and anaesthetic nursing staff have at least a medical training, support care staff are often career changers from non-medical professions.
Support carers who participated in the operating theatre inspections, for example, had initial professional experience as trained animal keepers, postmen, car mechanics, pastry cooks or architects.

The recognised radiological protection training for operators (for fluoroscopy: type-B courses) has in the meantime been integrated into medical specialist training.
Up until now there is only one additional training opportunity for operating theatre personnel. It is available for specialists in surgical technology or to qualified nursing staff The inspections showed that this training was only rarely completed. Graduates of an IRA or PSI course were found in only four hospitals.

A structured introduction to the occupational handling of ionising radiation could help to provide or update a basic skill in radiological protection for the operating theatre personnel. The complete revision of the Radiological Protection Ordinance that came into force on 1 January 2018 stipulated the legal obligation for continuing education in radiological protection. In the inspections, this was pointed out and enquiries were made on whether introductions and continuing education were already regularly organised. This was answered to negatively in 84 out of 207 cases (40%). In various inspections, it was added that the training occurred infrequently or that not all professional groups were involved.
Encouragingly, foreign professionals in operating theatres regularly continued their training in their home countries (particularly in France and Germany) in order to maintain their radiological protection skills. These persons are employed in 11% of hospitals – particularly in regions close to the border.

4 Radiological Protection Ordinance of 26 April 2017 (Status on 1 February 2019); SR: 814.501: Article 19 paragraph 2

Quality assurance of the equipment, technical documentation

For each X-ray unit that is installed in a hospital a technical document corresponding to Article 17 (up to 31.12.2017: Article 5) of the X-ray Ordinance must be created. The documents that must be stored therein are likewise mentioned: licence application, radiological protection plan with shielding calculation, FOPH-licence and the protocols of all implemented tests and controls. The supplier and the person responsible for radiological protection are both accountable for the creation and management of the technical documentation. This may also be managed electronically. The responsible persons have to have access and the right to consult them.

In the operating theatre inspections, when possible, all technical documentation was looked at and examined. In hospitals with many X-ray units, all technical documentation was checked for completeness and some was inspected thoroughly.

About 20% of the technical documentation was found to be "not in order". They did not comply with the requirements of the X-ray Ordinance because *inter alia* the radiological protection plans, licences or application copies were missing. Other technical documentation could not be traced or could not be attributed to any particular unit.

The quotas for correctly implemented tests of protocols in the technical documentation were 90% for the acceptance test, 88% for the status check and 83% for the constancy test.

Additional observations of the operating theatre inspections

The assessments of the inspection reports identified the following findings. For easy reference, they are listed according to key points without any particular order of priority.

Organisation of the radiological protection of the staff in the hospital

- The awareness of licence holders with regards to their responsibility for a good radiological protection culture and a functioning organisation of radiological protection was clearly too low.
- Experts on X-ray units in the operating theatre were often employed in radiology. At best they had contact at the administrative level with the operating theatre. They were unaware of the work processes, routines and information requirements there.
- Problems often arose when there was a collaboration between the operating theatre and a radiological institute or a radiological department, in order to ensure the required expertise to obtain a licence from the FOPH.
- Frequently, too little or even no available time was allocated to the experts for tasks in radiological protection.

Training

- Only a few people who dealt with ionising radiation had received adequate training for their job.
- The topic of radiological protection was generally given low priority in specialised professional training. Individual training institutes have already reacted and the number of training hours in radiological protection has significantly increased, partly on their own initiative.
- Support care staff are mainly career changers, often with a non-medical background, and
- consequently without any training in radiological protection. Support care staff received from the manufacturer or supplier of the X-ray device the most extensive training, were instructed most intensively in operating the equipment, prepared the C-arm for the fluoroscopy and operated it in the operating theatre under the instruction of the physician.

Technical device settings

- In more than 68% of hospitals, no dose-reduction techniques (appropriate pulse rates, collimation) were used. Frequently stated justifications for this were time-management, high workload and "not wanted" by the physician.

Organisational processes, communication

- The medical users of ionising radiation were not sufficiently aware of their responsibility for the whole operating theatre team. Not only the operator, but rather the whole team, are exposed to the radiation. By optimising the radiation applications, the operator has the ability to reduce the exposure to an average of four to six people plus the patient.
- The information flow between radiology and the operating theatre was often deficient.

Dosimetry

- The awareness of licence holders that adequate personal dosimetry is also part of the duty of care was often lacking.
- For all professional groups who work in operating theatre, the understanding that personal dosimetry is also to be regarded as a means of self-protection was clearly not sufficiently developed.
- Dosimeters and protective clothing are part of the correct operating theatre clothing when working with X-ray radiation.

Conclusions of the FOPH

The assessment of the inspections clearly shows that there is a need for action in many areas. Individual points are summarised below by the subject area.

The breakdown and order of the various subject areas do not follow a particular priority. It serves only to facilitate the orientation.
A good radiological protection culture can only develop if interdisciplinary collaboration and collegial communication (e.g. operating theatre organisation, medical service, radiology) are cultivated. It lives from the fact that not only details complained about in inspections are taken into account, but also practice-oriented and compliant routines are implemented, processes are improved and the initiative of those involved is promoted.
Some subject areas also offer suggestions for continuing education course curricula for target groups.

“A good radiological protection culture can only be achieved and lived if the eye is open to the big picture.”

Organisation of the radiological protection of the staff

- Licence holders have to comply with legal requirements and employ an adequate number of experts.
- In order to establish a good radiological protection organisation in the operating theatre, the expert should work closely together with local delegates in the operating theatre and exchange information on a regular basis.
- If a collaboration is initiated between the operating theatre and a radiological institute or department in order to ensure the necessary expertise for the granting of FOPH licences, the radiation protection experts deployed must be guaranteed direct access (e.g. their own badge) to the operating theatre at all times and the necessary competencies to issue instructions to those working in the operating theatre.
- With the appointment of experts, the licence holders also have to provide the necessary means (employment percentage, competence to issue directives, work materials).
- In-house delegates in the operating theatre who perform radiological protection duties under the responsibility of radiological protection experts must also receive the necessary resources with the delegation.

General organisation of radiological protection in the hospital

- In the supervised area, dosimeters and suitable protective means must be worn consequently. When dealing with ionising radiation, they belong to the basic equipment just like the typical work clothing in the operating theatre.
- The licence holder must ensure that X-ray systems are operated in compliance with the law. This also includes that visiting GPs must behave accordingly in radiation protection matters.
- The exposure of staff and patients should follow the basis of ALARA – as low as reasonably achievable.
- Radiological protection duties must be stipulated in writing in internal directives. Internal directives have to be reviewed regularly to ensure that they are up to date and adjusted if necessary.
- The regulations in the operating theatre must also follow a risk-based approach. Correspondingly different regulations must be made for the operation of a C-arm in the low-dose range and a C-arm in the high-dose range. The regulations must be noted in an internal directive.
- Technical documentation must be created in full. If many X-ray devices are operated in one operating theatre and their use is authorised in the same rooms, then a complete set of the radiological protection plans can also be stored in a separate folder (instead of individual ones).

Structural radiological protection

- Structural radiological protection must be carried out according to the radiological protection plan. For this, the technical radiology protection expert must check the on-site compliance, label additional shielding with Pb-equivalent values and mark the approved rooms as supervised areas (radiation warning signs and the indication of the type of radiation).

Training

- Support care staff should also have a clearly defined minimum knowledge of radiological protection that is relevant to their field of activity.

Continuing education

- The licence holder or the technical radiological protection expert must prepare a continuing training concept in radiological protection for the occupationally exposed persons of the hospital.
- Continuing education in radiological protection should be specific to the profession and have a content targeted to particular activities.
- Equipment training should be adapted to the existing knowledge and current questions of the personnel and should not be carried out as a repetition course.
- Further training in radiological protection in the operating theatre has to be practice- and application-oriented as well as tailored to the needs and questions of the operating theatre personnel. The required acceptance can only be achieved in this manner. The operating theatre staff can sensibly adapt their work processes in dealing with ionising radiation.

Technical device settings

- The omitted use of dose-reduction techniques cannot be tolerated from the viewpoint of radiological protection. If necessary, equipment training is useful to train doctors and nurses in the use of the correct collimation. Medical physicists can also provide support and show in training courses how the radiation exposure can be significantly reduced by the settings of the equipment.
- The users must pay significantly more attention to equipment settings.
- When the C-arm is delivered and transferred to routine operation, defined programs are to be stored and saved as required by the user. These programs have to be technically optimised and adapted as far as possible.
- From the point of view of radiation protection, close cooperation between surgeons, manufacturers and suppliers and medical physicists in the creation of optimised programs for C-arm use is absolutely essential.
- A fluoroscopic unit without a live DAP display on the monitor may only be used in the low-dose range or must be upgraded or replaced.

Organisational processes, communication

- The responsibility for the justification of radiation use must be established locally in the operating theatre. The expert knowledge from radiology should be consulted in a supportive manner.
- A perfect communication between the operating theatre and radiology is essential. This is the only way to ensure reliable knowledge transfer in both directions.
- For administrative reasons, the FOPH may sometimes change the licence numbers. This can happen, for example, when a unit is transferred to another location or if it is included in a pool of mobile units. In this case, the hospital must inform the service technician or the manufacturer or supplier that the licence number has been modified. Otherwise, this may lead to inconsistences in the documents in the technical folders.

Dosimetry

- The results of personal dosimetry must be regularly analysed and communicated to the staff working in the operating theatre. Increased personal doses on the under-apron dosimeter may indicate defective protection means or result from the dosimeter being worn incorrectly.

Means of protection

- Costs for acquiring and inspecting protection means are at the charge of the licence holder.
- The protective means used for the staff and patient should be selected according to their application. A thickness of 0.25 mm lead-equivalent is usually sufficient in the operating theatre.
- The means of protection should be long enough to effectively protect the legs. They should not have openings that are too large (particularly in the armholes) and should fit each body size and stature.
- A thyroid protector is recommended for all operators and assistants who stand close to the table.
- Wrap-around means of protection are more suitable than one-sided front aprons for operating theatre staff.
- The means of protection must be inspected at least once a year. It must not lead to an additional exposure of personnel, regardless of who performs it. This also applies when a radiation protection apron is worn during the inspection.

Recording the exposure parameters

- For applications in the medium and high-dose range, documentation is required by law.
- The automated creation and storage of a dose report for all patients is desirable – even if no images have been saved.

The presence of medical physicists

- The application of radiation in the operating theatre should be further optimised by the presence of medical physicists.
  The following task areas should be covered (not an exhaustive list):
  The following tasks should be covered (not an exhaustive list):

  Advice on technical questions when acquiring new equipment (selection of the appropriate modality and technology)
  Optimisation of standard programs
  Awareness and training of staff for equipment settings
  Explanations concerning pregnancy (patients, staff) in the operating theatre
  Implementation of the ALARA principle – appropriate dose reduction for appropriate image quality.
- The technical development and the corresponding equipment of operating theatres require the attention of all participants. When applying new techniques or modifying the modality, checks must be made on the extent to which staff will be exposed to. Accordingly, temporary double dosimetry may be indicated for better estimation of the effective dose and the eye lens dose. As a rule, "best practice" descriptions in the internal directive must also be coordinated and adapted accordingly, and responsibilities must be reviewed and, if necessary, updated in accordance with the organisational chart. A medical physicist can provide support and assistance in this regard.

Legal bases for the inspections

Many regulations in healthcare are determined by cantonal provisions. Radiological protection is excluded from them.
The Federal Office of Public Health FOPH is the licensing and supervisory authority for medical X-ray equipment in Switzerland.
The legal basis for carrying out the inspections is formed by the Radiological Protection Act RPA of 22 March 1991, the Radiological Protection Ordinance RPO of 22 June 1994 (as of 1 January 2018: RPO of 26 April 2017) and the X-ray Ordinance XrO of 20 January 1998 (as of 1 January: XrO of 26 April 2017. Complementary to the above are the Dosimetry Ordinance of 7 October 1999 (as of 1 January 2018: Dosimetry Ordinance of 26 April 2017) and the FOPH guidelines in the field of X-ray equipment.

References

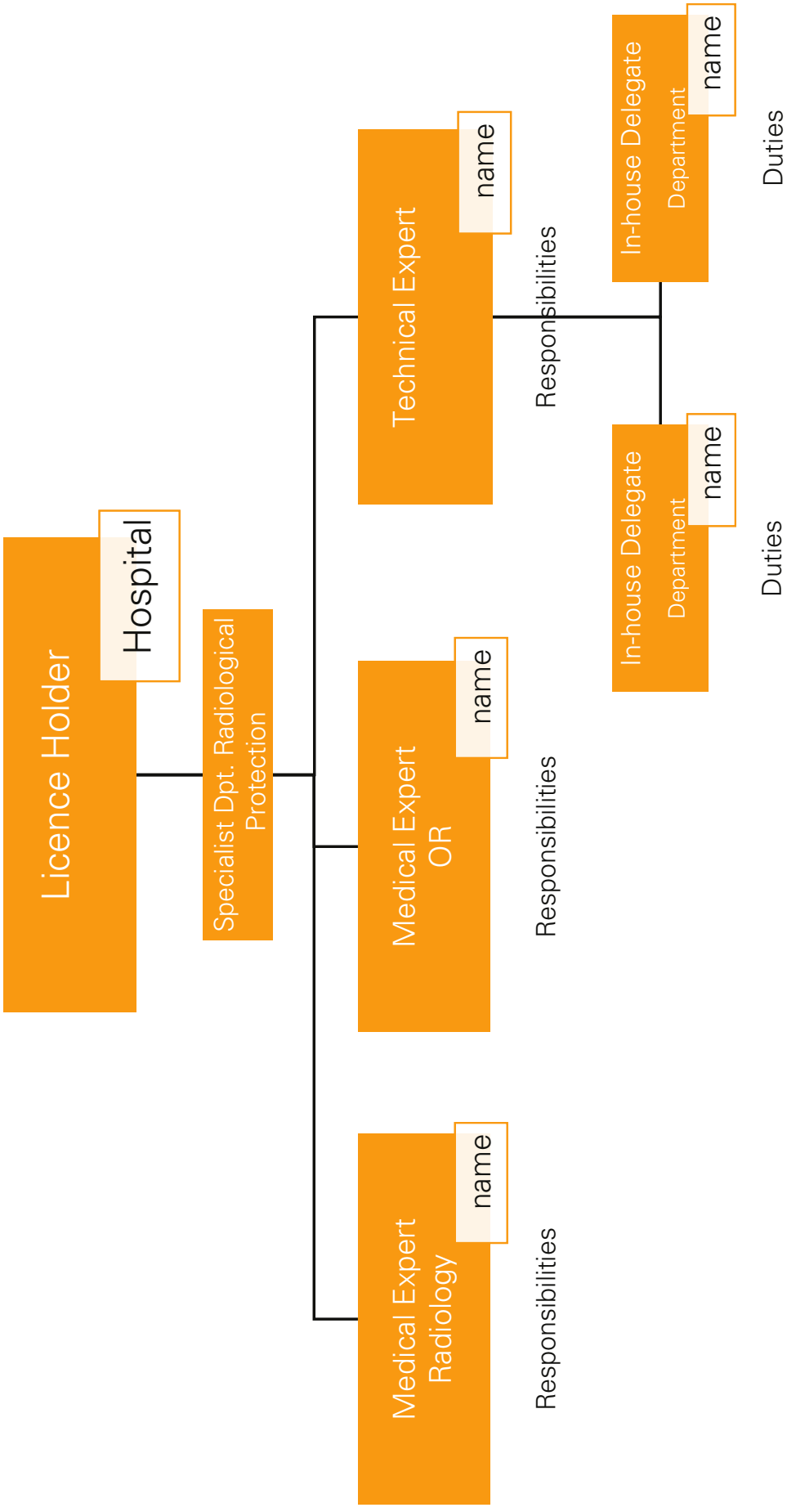
1. Radiological Protection Act RPA, SR: 514.50
2. Radiological Protection Ordinance RPO, SR: 814.501
3. X-ray Ordinance XrO, SR: 814.542.1
4. Dosimetry Ordinance, SR: 814.501.43
5. Radiological Protection Training Ordinance, SR: 814.501.261
6. FOPH Annual report Dosimetry 2017 (www.bag.admin.ch/str-jahresberichte)
7. FOPH Guidelines "SV Aufgaben"

Abbreviations

ALARA	As low as reasonably achievable
AN-Dr.	Physician medical anaesthetic staff
AN-care nurse	Non-medical anaesthetic staff
CBCT	Cone Beam Computed Tomography
CT	Computer tomography
DAP	Dose Area Product
Dipl.	Master degree
EOT	Expert for operation technology
ER	Expert for technical radiological protection
ER/Rad	Expert on medical application of ionising radiation on humans (specialist physician title for radiology)
ER/Surg	Expert on medical application of ionising radiation on humans (specialist physician title for a surgical medical discipline)
FOPH	Federal Office of Public Health
IRA	Institute of Radiophysics
kV	Kilovolt
mA	Milliampere
mm	Millimetre
mSv	Millisievert
MTRA	Specialist technician for medical radiology
PACS	Picture Archiving and Communication System
Pb	Lead
Physicist	Colleague from the department of medical physics
PSI	Paul Scherrer Institute
QM	Colleague from the department of Quality Management
RPA	Radiological Protection Act
RPO	Radiological Protection Ordinance
SSRMP	Swiss Society for Radiobiology and Medical Physics
SOP	Standard Operating Procedure
SR	Classified Compilation of Legislation
Support	Healthcare staff for operational support
Surgeon	Physicians of various specialities active as surgeons
TS	Colleague from the department of Technical Service and/or Medical Technology
XrO	X-ray Ordinance

Annex 1

Organisation Chart Radiological Protection



Annex 2

Subject list for internal radiological protection directives

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate

Radiological Protection in operations department
Internal Directive

- ➔ Definition of Responsibilities and Duties
  (Experts, in-house delegates), Organisation chart
  FOPH Guidelines "technical Experts duties"
- ➔ How Dosimetry is managed
  (Information flow
  Responsibility
  Which personnel,
  Double or multiple dosimetry
  Evaluation/analysis,
  Communication,
  external physicians)
  R-06-03
- ➔ Protection Means for Staff
  (Acquisition, inspections, disposal
  Obligation to wear protective equipment)
  R-09-02
- ➔ Protection Means for patients
  (Acquisition, inspections,
  possible applications)
  R-09-02
- ➔ Introducing new colleagues to radiological protection
- ➔ Training/continuing education
  (continuing education concept, mandatory continuing education, responsibility, frequency)
- ➔ Dealing with pregnancy
  (internal rules,
  2nd dosimeter?)
  R-05-01
- ➔ Best Practice
  (Opportunities for radiological protection in the daily routine)
- ➔ Basics, legal provisions