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Integrated assessment of radiation safety in health and medical services

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Foreword

The Swedish Radiation Safety Authority (SSM) has conducted an integrated assessment of radiation safety in health and medical services. This report provides a summary account of compliance with legislative requirements and conclusions drawn from the level of compliance achieved, as well as an assessment of radiation safety in health and medical services. The assumption is that a work activity is safe as long as the applicable legislation and regulations are complied with. This report is based on the results from compliance inspections of practices involving ionising radiation within nine county councils. The report is mainly directed at decision-makers at various levels of Swedish county councils: politicians, officers and directors. It also offers knowledge to various professions in health and medical services. The report is based on the injunctions issued by the Swedish Radiation Safety Authority in connection with compliance inspections.

The Swedish Radiation Safety Authority has also performed follow-up inspections within five of the nine county councils. The results from these follow-up inspections have not been compiled; however, the Authority has drawn the conclusion that improvements in radiation safety were made on the part of several county councils between the time of the first compliance inspection and the follow-up inspection.

Radiation safety is an umbrella term and which, in terms of medical practices, encompasses radiation protection, safety and physical protection (security).

Radiation protection refers to protection of people and the environment against harmful effects of radiation by performing justified and optimised examinations and therapy and by applying dose limits to staff and the general public.

Safety refers to protection against harmful effects of radiation through high standards for the prevention of failures in equipment and incorrect action that can lead to an accident, in addition to limiting injuries if an accident takes place nevertheless.

Physical protection implies protection against unauthorised access to premises, unauthorised use, theft, sabotage of equipment or radioactive material or other impact that could imply harmful effects from radiation.

Structure of this report

Chapter 1 contains an introduction including the report's aim, the assessment method and related delimitations. Chapter 2 describes the practices involving ionising radiation occurring in health and medical services. Chapter 3 provides an overall account of the requirements imposed on activities involving medical exposure. Chapter 4 provides a summary account of compliance with the requirements imposed on radiation safety in health and medical services. Chapter 5 presents a risk evaluation. Based on the summary account of compliance, Chapter 6 presents conclusions drawn on the implications for different work activities and practices in health and medical services. Various concepts and abbreviations are explained in the section about definitions and abbreviations. The Appendix contains the underlying information compiled for this report.

Summary

The county councils do not meet the Swedish Radiation Safety Authority's requirements in terms of radiation safety. This implies that their health and medical services have deficiencies in this area that could lead to serious consequences for patients and staff, a conclusion based on the Swedish Radiation Safety Authority's compilation of information from the nine county councils that underwent the inspections. The starting point for radiation-safe health and medical care is that all medical exposure is justified and optimised, and that dose limits for staff and the general public are not exceeded. In brief, this means that radiation must not be used unnecessarily and that the dose for people must be as low as possible while at the same time achieving the results intended. Radiation-safe health and medical care presupposes that applicable legislation and regulations are complied with.

There were considerable deficiencies in the inspected county councils' organisation, management, follow-ups and development of their work involving radiation, which is deemed as the root cause of non-compliance with other requirements as well. Above all, the responsibility for radiation safety work did not follow the organisational structure, bringing about a situation where there was a lack of authority for decision-making in this area. In its turn, this situation implied an elevated risk of deficient or incorrectly performed examinations and therapy.

None of the county councils that underwent the inspections performed systematic evaluations of radiation safety work, resulting in the upper management of the county councils and hospitals being unaware of these deficiencies.

Due to the low level of compliance with legislation, the county councils could not ensure that medical exposures were justified and optimised. They could not ensure that medical exposures were performed in accordance with the established working procedures. The compliance inspections performed in 2011, but not yet compiled, show the same deficiencies. This has led to the Swedish Radiation Safety Authority being of the view that health and medical services fail to meet radiation safety standards.

The deficiencies described by this report imply an elevated risk of serious side effects as well as acute and delayed radiation injuries. The level of severity of these consequences depends on the radiation dose to the patients or staff, in addition to the number of individuals who are exposed to the radiation. A low level of radiation safety is correlated to the highest level of risk posed by radiotherapy, where powerful radiation doses are given to patients. This also applies to the more than five million X-ray examinations performed annually.

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1. Introduction

1.1. Aim

The aim of this report is to improve radiation safety in health and medical services by shedding light on commonly occurring deficiencies and communicating them to the parties carrying out these activities and practices, i.e. the licensees.

1.2. Method

This report provides a compilation of the instances of non-compliance identified by the Swedish Radiation Safety Authority by means of investigations and regulatory supervision of practices involving ionising radiation in health and medical services. The assumption is that a work activity involving radiation is conducted safely as long as the applicable legislation and regulations are complied with. An integrated assessment of radiation safety uses the observed deficiencies on the part of the respective county council in relation to applicable regulations as a platform for making a comparison with the other county councils that underwent the inspections. This painted a composite picture of the situation in terms of radiation safety in Swedish medical care. The Authority used the results of this compilation to analyse root causes of and links between the various deficiencies observed with the aim of enabling an integrated assessment of radiation safety while also contributing toward improved radiation safety in the future.

1.3. Delimitations

This report is based on the results from compliance inspections of medical practices at nine county councils in Sweden between 2005 and 2010. These inspections involved looking into overall activities involving ionising radiation, from how the work is managed and controlled to how the work is performed in practice. The report excludes odontological work at the nine county councils, nor have aspects pertaining to physical protection (security) been taken into account in this assessment. Inspections were performed within the following county councils:

a) Jämtland County Council
b) Västernorrland County Council
c) Stockholm County Council/Karolinska University Hospital in Solna
d) Jönköping County Council
e) Gävleborg County Council
f) Halland County Council
g) Värmland County Council
h) Västmanland County Council
i) Kronoberg County Council

2. Ionising radiation in the care sector

Practices involving ionising radiation in health and medical services can be broken down into X-ray diagnostics, nuclear medicine and radiotherapy.

At the 250 medical care establishments in Sweden conducting activities involving ionising radiation, 5,400,000 X-ray examinations and 100,000 nuclear medicine examinations are performed annually. Each year, 28,000 patients receive radiation treatment, of whom 2,500 receive nuclear medicine therapy. Health and medical services encompass an estimated 12,000 people working with activities involving ionising radiation.

A party using ionising radiation in examinations and treatment of patients must have a licence from the Swedish Radiation Safety Authority. The Authority's licence records currently contain 148 licences for medical practices involving ionising radiation. Of these, 89 licensees conduct X-ray practices, 26 radiotherapy and 33 nuclear medicine practices. Altogether, these licensees own more than 2,100 pieces of X-ray equipment, 100 pieces of radiotherapy equipment and around 100 pieces of equipment for nuclear medicine diagnostics.

2.1. X-ray imaging

X-ray diagnostics consist of conventional X-ray examinations, invasive procedures and computed tomography (CT). Invasive procedures are forms of treatment performed using X-ray guidance, also called 'fluoroscopy'. A CT scan is a kind of examination that is often called a 'CAT' scan, for 'computerised axial tomography'. Besides at X-ray departments, X-ray diagnostics and invasive procedures are performed at other clinics or wards such as emergency admissions, surgery wards and others.

The average dose from an X-ray examination varies depending on the technique and kind of examination as shown in Table 1:

Technique	*Conventional X-ray examinations*	*Computed tomography*	*Invasive procedures*
Average dose	0.05 to 6 mSv	2 to 10 mSv	12 mSv

Table 1. Average dose from different kinds of X-ray imaging procedures, in millisievert (mSv).

Invasive procedures give the highest average radiation dose. There is a risk that these procedures cause acute radiation injuries in the form of reddened skin, hair loss and, in a worst case scenario, sores that are slow to heal.

The number of computed tomography examinations has risen considerably, currently amounting to approximately 15 per cent of the total number of X-ray examinations and representing as much as around 70 per cent of the radiation dose from all X-ray examinations.

2.2. Nuclear medicine

Nuclear medicine encompasses examinations as well as treatments. Nuclear medicine examinations (also referred to as isotope diagnostics) and therapy make use of radioactive pharmaceuticals that target a certain organ or certain kind of tissue. Nuclear medicine examinations normally give radiation doses between 1 and 10 mSv depending on the kind of examination. Nuclear medicine therapies may give rise to a high radiation dose surrounding these patients, meaning that staff, family members and the general public risk being exposed to relatively high radiation doses unless restrictions on socialising are complied with. Diagnostics using positron emission tomography (PET) scans, linked to high levels of activity and thus high occupational radiation doses, have since 2005 increased by approximately 20 per cent per year.

2.3. Radiotherapy

Each year, more than 50,000 new cases of cancer are diagnosed. The number of diagnosed cases of cancer is increasing each year. One key reason is the increasing number of older people. Half of all cancer patients receive radiotherapy at some stage. This is a 50 per cent increase since the early 1990s [1]. Radiotherapy gives significantly higher radiation doses than X-ray examinations and nuclear medicine examinations because the point of the treatment is to kill cancer cells. The very high radiation doses give the individuals side effects from the radiotherapy. Deficient or incorrectly performed radiotherapy can lead to unnecessary side effects and lifelong suffering for a patient.

2.4. Staff at risk of receiving high radiation doses

The people who are mainly at risk of receiving high radiation doses are staff in nuclear medicine and staff performing invasive procedures; a risk that can lead to detriment, such as cataracts, for example. The main limits prescribed that might be exceeded are those for the fingers, hands and eyes, despite the optimisation of radiation exposure.

3. Legislative regulation

The starting point for radiation-safe health and medical care is that all medical exposure is justified and optimised, and that dose limits for staff and the general public are not exceeded. In brief, this means that radiation must not be used unnecessarily and that the dose for people must be as low as possible while at the same time achieving the results intended. Radiation-safe health and medical care presupposes that applicable legislation and regulations are complied with.

Parties conducting activities involving ionising radiation must fulfil the requirements of the Radiation Protection Act (1988:220) and Radiation Protection Ordinance (1988:293), in addition to regulations issued by the Swedish Radiation Safety Authority. The aim of the Radiation Protection Act is to protect people, animals and the environment against harmful effects of radiation.

3.1. Requirements imposed on medical exposures

The work to assess justification and optimisation of medical exposures presupposes an organisation with the capacity to learn continuously from its experiences with the aim of improving its operations. Prerequisites include sound knowledge about outcomes, difficulties and targets, as well as the organisation's work being systematically evaluated and developed.

This is why the Swedish Radiation Safety Authority requires county councils in Sweden to maintain clear-cut control and management of radiation safety work, have sufficient resources for this work and clearly documented routines, procedures and methods, as well as these county councils systematically following up, evaluating and developing their work.

3.1.1. Justification

Medical exposures are to signify more benefit than detriment for patients, while at the same time taking into account that staff and other persons involved must not be exposed to an unnecessarily high level of risk. The party in charge of the work activity must, under these requirements, ensure that all radiation exposure is justified:

- All new methods or applications must have been determined to be justified before their general use. The objective is to determine whether the method can improve diagnosis or treatment. To make it possible to correctly determine justification of new methods, often using new and advanced technical apparatus, great demands are placed on knowledge about clinical research and new research findings.

- All separate medical exposures must be determined in advance to be justified, while taking into account the specific objectives of the radiation exposure and the health situation of the individual patient.

Determination of new methods' or applications' justification and the design of routines for justification of separate radiation exposures must have involved a specifically appointed specialist physician who is an expert (practitioner, or holding the 'radiological leadership') in the relevant field (X-rays, nuclear medicine and radiotherapy).

3.1.2. Optimisation

Systematic work on optimisation of radiation exposure situations is an essential part of conducting radiation-safe practices. In brief, the concept of optimisation refers to:

- The process of minimising the radiation dose to patients, also to staff or family members accompanying the patient during the examination, while at the same time receiving diagnostic information
- The process of adjusting the radiation dose to the individual patient so as to achieve the intended effect from treatment while keeping the radiation dose to healthy tissue as low as reasonably achievable

Dose limits for staff and the general public must not be exceeded. Optimisation work must take into account aspects such as shielding rooms from radiation, the choice of equipment, choice of methods of treatment or examination as well as practical implementation. Systematic and satisfactory optimisation work requires an excellent capacity to organise, evaluate and improve the activities.

The Swedish Radiation Safety Authority's regulations impose specific requirements on the combined responsibility of the practitioners ('RLF' in Swedish) and authorised medical physicists (medical physics experts) to ensure good performance of optimisation work for the purpose of achieving a good level of radiation protection for patients.

3.1.3. Organisation of radiation protection

The requirements stipulate that the organisation of radiation safety work must be documented. The description must include an account of how tasks are assigned and the parameters for co-operation between county council and hospital management, supervisors, expert roles and other relevant staff. The organisation must have appointed three expert roles: the practitioner, radiation protection expert and radiation protection committee. The practitioner must be a specialist physician in the relevant field (X-rays, nuclear medicine and radiotherapy), and the radiation protection expert (also called the 'qualified expert') must be an authorised medical physicist. One or more authorised medical physicists are also required, who are knowledgeable in the same fields. The expert roles and medical physicists must comply with the requirements on (for example) working with specified tasks concerning justification and optimisation, as well as staff training.

3.1.4. Resources

Radiation-safe medical care presupposes the licensees ensuring that all staff working with medical exposures have the necessary competence for safe performance of their tasks, also that equipment and premises are adapted for their purposes.

Competence of staff

Sufficient competence is essential for ensuring radiation-safe work and a good work environment. All staff are required to possess the theoretical and practical skills necessary to ensure that the practice can be conducted in an environment offering good radiation protection.

Programmes for introductory training, in-service training and continuing education are key tools that ensure staff competence. Documented descriptions of arrangements for training of relevant staff in radiation protection, methods and procedures must be in place. This documentation must clearly state the steps of training required for different categories of staff as qualifications to perform a certain task. Documented routines must also be in place on identification of the need for training, in addition to documentation on which members of staff have completed the training. All training that has been completed is to be undersigned on a record by the respective staff member.

Equipment and apparatus

One important factor is the use of suitable equipment and apparatus in the practice. The procurement process must take into account the requirements imposed on radiation safety; also, a medical physicist is required to participate. Moreover, all pieces of equipment must be inspected regularly to ensure their radiation safety, in other words that all parameters and steps that can have an impact on the radiation dose and intended function are to be checked. Identified deviations must be subject to pre-existing and documented action plans.

Premises and rooms

Premises and rooms in which ionising radiation is used must be built so that the prescribed dose limits are not exceeded for persons present outside these areas. The design of radiation shields must be shaped depending on the kind of activity taking place in the premises or room, i.e. the level of potential radiation dose, the frequency of exposure in these areas as well as how often the general public or staff are present outside these areas. Documentation must be available on the premises' radiation shield system in addition to calculations and measurements showing that the prescribed dose limits are not exceeded. Workspaces must also be divided into categories, a *controlled* or *supervised area*, in order to protect staff from high radiation doses. A controlled area shall be delineated, marked with signs and access restricted to authorised persons only. A supervised area must be guarded and marked with signs. Persons with an expert role in radiation protection are the authorised medical physicists, who are responsible for planning and checking to ensure that the relevant premises or rooms are radiation safe.

3.1.5. Quality management systems

A system that assures work quality (quality assurance manual or quality management system) is to serve as a tool for meeting the requirements imposed on the activity. The requirements stipulate that a quality assurance manual on radiation protection must be available. This manual should be an integral part of the management system governing quality and patient safety. The quality assurance manual must clearly state how systematic radiation safety work is conducted, that is, that processes and routines must be in place defining how the organisation is to manage, document, inspect, follow up and audit its operations. It must also be clearly stated how documents are produced, examined and approved; also, where approved documents are retained and how they are communicated to fellow employees.

Working procedures

The Swedish Radiation Safety Authority imposes particular requirements on documented and approved protocols to ensure that treatments and examinations are performed in accordance with quality assured methods and that special considerations are given to children and pregnant patients.

3.1.6. Audits of practices

The Swedish Radiation Safety Authority requires licensees using ionising radiation in medical care to systematically perform audits of their clinical radiological procedures and routines in relation to established working procedures for good care. The purpose of audits is to raise the quality of work and care results. An audit can also increase awareness of quality, identify outdated methods and improve standards.

3.1.7. Managing deviations

Identifying, documenting, investigating and reporting incidents, as well as determining and dealing with the root causes, make up a key component of organisational development. Another important aspect is to evaluate measures that have been taken to check that they had the intended impact. Incidents are to be recorded and a list of them redistributed to employees and other relevant persons. Experience gained when managing deviations is to be used as part of preventive risk management. Medical physicists must take part in investigations into incidents. Current requirements also stipulate that incidents of relevance for radiation protection purposes are to be reported as soon as possible to the Swedish Radiation Safety Authority.

3.1.8. Protection of patients

One’s capability to perform measurements, calculations and registration of radiation doses to patients from examinations and treatments is essential for optimisation work.

Radiation doses to patients from examinations

In connection with examinations, the diagnostic standard dose, in other words the established radiation dose for a particular kind of examination, is to be determined for the examinations for which the Swedish Radiation Safety Authority has set diag-

nostic reference levels. If the reference levels are exceeded, the cause must be investigated and relevant actions taken in order to reduce the dose. Protocols are to cover suitable measures to reduce doses. Routines must also be in place for identification and follow-ups of patients who might develop acute radiation injuries following invasive X-ray procedures using fluoroscopy. Fluoroscopy allows staff to use monitors for direct viewing of X-ray images while the invasive procedure is taking place.

Radiation doses to patients from therapy

By checking all parameters relevant to the treatment and radiation dose received by a patient, one ensures that the treatment is as planned. The requirements stipulate that routines must be in place for different kinds of checks for quality assurance of therapy and routines for procedures to prevent predictable errors that might imply unintentional or incorrect radiation exposure.

3.1.9. Protection of staff

The Swedish Radiation Safety Authority requires licensees to perform measurements of individual doses for all employees who are at risk of receiving high radiation doses in order to verify that the staff are not exceeding the prescribed dose limits.

3.1.10. Protection of family members and supporting persons

Routines must be in place on suitable measures and precautions to be taken with the aim of minimising exposure to supporting persons. The radiation dose to supporting persons is to be as low as reasonably achievable considering the circumstances. There must be routines for patients who have received treatment using radioactive material to ensure that the applicable dose constraints for family members are not exceeded.

4. Summary assessment of compliance

At the time of the compliance inspections, the county councils that underwent the inspections were not complying with the requirements imposed by legislation and regulations. Consequently, the Swedish Radiation Safety Authority has drawn the conclusion that the county councils cannot ensure that practices involving radiation are justified and optimised.

Justification

In the area of radiotherapy, individual assessments of justification were made on the part of all the county councils in connection with confirmed cancer diagnoses of patients. Five out of the nine county councils lacked routines or had deficiencies in them when it came to assessing justification of diagnostic examinations. These routines mainly lacked criteria or guidelines for justification, meaning that the assessments were based on the knowledge of individual doctors.

In a national study of computed tomography examinations [2], the Swedish Radiation Safety Authority has drawn the conclusion that assessments of justification show major shortcomings. The study showed that 20 per cent of the examinations performed were considered to be non-justified, corresponding to excessive irradiation equivalent to 800 manSv.

Optimisation

In the area of radiotherapy, all the county councils carried out optimisation work, but lacked routines for systematic evaluations of clinical results. In diagnostic work, no systematic optimisation work took place; instead, this was only performed sporadically as part of separate projects or only in certain parts of the organisation. According to an SSM report [3], there is a broad spread of radiation doses between hospitals when it comes to all of the kinds of examinations. This situation indicates that many examinations have not been optimised.

Radiation protection of groups such as staff and family members

A key prerequisite for optimisation of radiation doses to staff is a risk analysis of occupational situations and working procedures that among other things leads to categorisation of all staff working in practices involving ionising radiation. Eight out of the nine county councils had deficiencies in their system for categorisation of staff. As a consequence, incorrect measures are taken and the wrong decisions are made when optimising staff radiation doses.

Two out of the nine county councils had deficiencies in their routines for radiation protection measures to be observed on the part of family members and supporting persons. These deficiencies were found in X-ray practices.

The Swedish Radiation Safety Authority has observed that all the county councils had key persons available (such as oncologists, radiologists and medical physicists) skilled in conducting justification assessments and optimising examinations and therapy. The identified deficiencies in terms of the radiation protection of patients and staff, and of family members or supporting persons, were largely due to the

county councils not fully complying with the regulations whose purpose is to improve the potential for succeeding with this work. The Authority presents the licensees' fulfilment of the requirements in this chapter.

4.1. Summary account of compliance

Altogether, the county councils that underwent the inspections showed deficiencies in all areas. A few individual county councils fulfilled the requirements to a greater extent than the others; however, the difference was marginal.

Figure 1 shows the level to which the nine county councils that underwent the inspections altogether fulfilled the requirements (grouped by area as broken down in Chapter 4) imposed on health and medical services and that, from the inspections, led to injunctions requiring action.

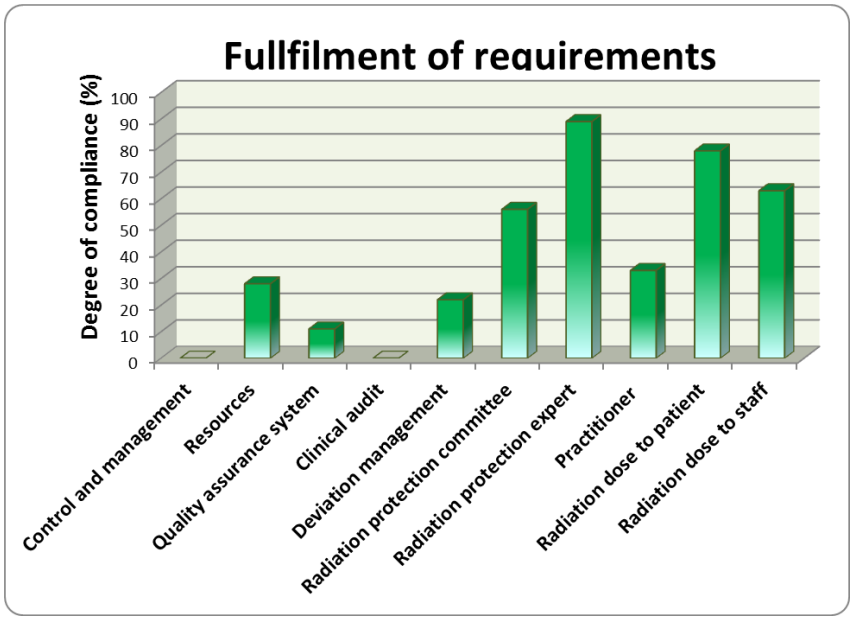

Figure 1. Total level of compliance achieved by the nine county councils that underwent the inspections.

All the county councils had deficiencies in their control and management of radiation safety work. There were (for instance) major shortcomings in the county councils' quality management systems and their systems for dealing with deviations. There was often a lack of routines and guidelines for managing, investigating and dealing with deviations, in addition to assessment criteria for measures and reporting to the Swedish Radiation Safety Authority.

The fact that the county councils altogether fulfilled the requirements imposed on resources to a level of only 30 per cent was mainly due to deficiencies in county council training programmes. It was common for many members of staff to lack training in practical and theoretical radiation protection as well as equipment handling.

Requirements on verifying the radiation dose to patients and categorised staff were largely fulfilled by the county councils. However, they failed to measure the radiation dose to the staff's eyes and hands to the required extent.

A more detailed summary account of the county councils' compliance with the requirements is provided below.

4.1.1. Justification

In the area of radiotherapy, individual assessments of justification were made on the part of all the county councils in connection with confirmed cancer diagnoses of patients. Established programmes of care cover the most common cancer diagnoses. The question as to whether or not radiotherapy is justified depends on factors such as the cancer diagnosis and what is stated in the care programmes. A patient's treatment plan, where radiotherapy is one of several methods, was produced when assessing its justification. All the county councils participated in various national or regional care programmes.

Individual justification assessments in connection with diagnostics are more complex. Referrals are written and assessed by different categories of professions with different expertise. A correct assessment of whether an examination is justified presupposes that the person deciding on radiation treatment is skilled in different diagnostic methods and that the case is clearly evident. Five out of the nine county councils lacked routines or had deficiencies in them when it came to assessing justification of diagnostic examinations. These routines mainly lacked criteria or guidelines for justification, meaning that the assessments were based on the knowledge of individual doctors.

In an investigation of computed tomography examinations [2], the Swedish Radiation Safety Authority has concluded that assessments of justification show major shortcomings. This investigation revealed the following:

- Of all the county councils, 84 per cent stated that they had documented routines for managing referrals in accordance with the requirements of the National Board of Health and Welfare ('SoS')
- 36 per cent of the departments stated that they had documented routines for assessing justification
- 65 per cent of the departments stated that they assessed justification for all referrals
- 20 per cent of the examinations performed were not assessed to be justified

The fact that one out of five examinations was performed needlessly represents excessive irradiation corresponding to 800 manSv.

In addition, the Swedish Radiation Safety Authority has, by means of a communication from the European Commission [4], observed deficiencies in the EU when it comes to assessing justification of new methods. According to the European Commission, equipment is occasionally marketed and implemented using new and advanced methods, but without sufficient evidence that the benefit outweighs the risks. For example, new techniques in radiotherapy have been implemented on a large scale, but without sufficient evidence that they raise the survival rate of cancer pa-

tients, nor their quality of life. New diagnostic equipment is also implemented without sufficient justification, often before relevant quality assurance procedures and continuing training programmes for the staff concerned have been implemented.

4.1.2. Optimisation

At the time of the compliance inspections, all the county councils had deficiencies in their optimisation work due to deficiencies in their radiation shield system for premises and rooms, equipment handling and practical implementation of examinations and treatments.

Optimisation work is strongly correlated to audits of practices, which none of the county councils performed systematically. In the area of radiotherapy, all the county councils carried out optimisation work, but lacked routines for systematic evaluations of clinical results and systematic audits of procedures. Following their treatment, the patients often return to the referring caregiver, thus complicating follow-ups of potential side effects and evaluations of the clinical results.

In diagnostic activities, no systematic optimisation work took place; instead, this was only performed sporadically as part of separate projects or only in certain parts of the organisation. According to an SSM report [3], there is a broad spread of radiation doses between hospitals when it comes to all of the kinds of examinations. This situation indicates that many examinations have not been optimised.

4.1.3. Organisation of radiation protection

At the time of the compliance inspections, all the county councils that underwent them showed indications of serious deficiencies in their control, management and follow-ups of radiation safety work. Several of these deficiencies were of a cross-cutting nature encompassing all the relevant areas of operations. Examples included:

- The description of how radiation safety work was organised was often out of date and did not reflect how the work was performed
- The experts' roles, tasks and authority were often unclear
- The radiation safety organisation and its implications were unknown in the organisation

In most of the county councils, the allocation of radiation safety work did not follow the organisational structure. To mention one example, the medical physicists had an overall responsibility for radiation protection training in all practices involving ionising radiation, but without the authority to take decisions on staff training in these practices. The unclear allocation of responsibility and tasks resulted in the non-performance of several tasks and consequently their failing to fulfil the requirements imposed.

All the county councils' organisations had a medical physicist as an expert on radiation protection. There was nonetheless a lack of clarity when it came to allocation of responsibility and the authority to take decisions on matters of radiation safety relating to staff, between medical physicists and the supervisor in charge of staff. Radiation protection of staff was not considered to be a work environment category, re-

sulting in the supervisor in charge of staff failing to take radiation safety aspects into account. Instead, the medical physicist was considered to be in charge, though without the authority to take a decision in these areas. As a consequence, the occupational environment failed to achieve a satisfactory level and the licensee could not guarantee that the staff were working in a radiation-safe environment.

The county councils differed in their appointment of the practitioner, the activities covered by the assignment, as well as the tasks linked to the assignment. However, an aspect that they shared was that the requisite co-operation between the medical physicists and practitioners seldom worked in practice. In particular, it was the practitioner who did not actively take part in developing methods nor designing training programmes.

All the county councils had appointed radiation protection committees, but in most of the county councils, those who were practitioners did not participate in these committees, with the result that not all practices were represented. In its turn, radiation safety risked being neglected at these clinics.

4.1.4. Resources

Radiation-safe medical care presupposes licensees ensuring that all staff have the necessary competence for safe performance of their tasks, also that equipment, premises and rooms are fit for purpose.

Competence of staff

All the county councils that underwent the inspections had deficiencies in their training programmes. The most serious shortcoming was that physicians, above all those working with fluoroscopically-guided procedures in connection with different kinds of invasive procedures, were neither trained in radiation protection nor handling of this kind of equipment. There were also deficiencies in the county councils' reporting and follow-ups of the training opportunities. One observation from the compliance inspections was that the refresher course programmes tended to cover too many areas, often leading to the supervisors and staff not prioritising their attendance.

Two reasons behind the deficiencies in the county councils' training programmes were their unclear organisation and inadequate allocation of responsibility. One example mentioned earlier was that the medical physicists had an overall responsibility for radiation protection training in all practices involving ionising radiation, but lacked the authority to take decisions on staff training in these practices. This led to a situation where the training programmes were not held to a sufficient extent and the staff did not attend the training opportunities. In the practices where training requirements were complied with, the supervisor was in charge of ensuring his or her subordinates' competence.

The deficiencies of the training programmes implied that the county councils could not ensure that their staff had sufficient professional skills for their tasks. This was the case not only for introductory and refresher courses on procedures, but also on local radiation protection and use of equipment. If staff lack the practical skills needed for safe performance of their tasks, there is a major risk that errors will be made having a serious impact, such as acute radiation injuries, for example.

The fact that all staff working with fluoroscopy, such as orthopaedists, surgeons and cardiologists, lack training in radiation protection is a particular concern, as these examinations often give high radiation doses. At the same time, these professions' basic education programmes lack instruction on the risks posed by radiation, or only offer limited instruction.

Equipment and apparatus

Generally, the periodic inspections of the equipment and apparatus were effective. The most serious shortcoming was the lack of checks following service and repairs. Procurement of new equipment did not always take into account aspects of radiation safety; or in other words, procurement did not involve the participation of an expert role representing radiation protection (i.e. an authorised medical physicist).

Premises and rooms

Six of the nine county councils that underwent the inspections could not at the time of the compliance inspections ensure that the premises and rooms used for X-ray diagnostics and nuclear medicine fulfilled the requirements. They did not fulfil the requirements on documentation to ensure that the prospective dose from the practice to someone present outside the premises or rooms does not exceed the prescribed dose limit. The county councils could also not account for the premises' radiation shield system because of missing construction drawings. They also lacked routines for work on dimensioning and verification of radiation shield systems for X-ray and nuclear medicine premises and rooms and could consequently not guarantee that the general public was not receiving excessive radiation doses. There was often a lack of documentation showing that the premises or rooms had been categorised correctly; also, documentation was lacking on safety routines. The premises and rooms used for radiotherapy were, on the other hand, designed in a way that was radiation safe and which fulfilled the requirements.

One of the reasons behind the deficiencies in the radiation shield system of premises was that the requirement on a medical physicist's planning for and checks of radiation safety in connection with refurbishing, rebuilding and new construction work was often unknown in the organisation. This implied that medical physicists neither participated in nor were involved in the building process, in its turn often leading to omitted measurements and calculations of the premises' radiation shield system.

Premises lacking a radiation shield system increase the risk of unintentional exposure of staff and the general public, thus increasing the risk of exceeding dose limits.

4.1.5. Quality management systems

All the county councils that underwent the inspections lacked quality management systems, or had deficiencies in them. However, a few individual practices involving ionising radiation had implemented local quality management systems that fulfilled the requirements imposed. This was particularly the case for practices in nuclear medicine.

The deficiencies were manifested in many areas, where it was unclear who was tasked with producing documents, so approved documents were often missing. Here,

the root cause was that many county councils lacked document management systems, or in other words processes and routines for the production, design and approval of documents, in addition to a description of where approved documents were kept and how they were communicated to the staff. Also, there were often no guidelines on the procedure and frequency of document audits.

There was also a lack of clear routines for follow-ups and audits of the practices and routines for liaison between the appointed expert roles, such as the qualified expert (radiation protection expert) and radiation protection committee, and the party that is ultimately responsible for the practice.

The lack of quality management systems makes it difficult for the county councils to check, evaluate and develop routines and working methods, so as a result, they cannot ensure that they are safely conducting a practice involving ionising radiation.

As a consequence, the respective licensee lacks documents demonstrating that:

- staff have sufficient competence
- the work is performed in accordance with established routines
- dose limits are not exceeded
- premises and rooms have an appropriate radiation shield system
- patients, staff and the general public are not exposed incorrectly or unnecessarily

As a result, these practices are conducted ineffectively without a sustained nor established level of quality and with an elevated risk of both an unhealthy work environment as well as incidents occurring.

Working procedures

There were major shortcomings in protocols for how examinations and treatments should be carried out. Not only were protocols missing, the staff did not always follow them.

Some of the reasons behind these deficiencies included unclear routines for producing and developing protocols as well as unclear allocation of responsibility. It was not clearly stated who was in charge of development, audits and implementation of present and new methods. Another reason was the lack of routines for document governance.

These kinds of deficiencies elevate the risk of unnecessary radiation exposure of patients, which above all can lead to delayed or acute injuries. This also increases the risk of patients receiving a radiation dose that is too low so that the diagnostic information becomes inadequate, which might lead to an incorrect diagnosis, or suboptimal therapy and ultimately poor results from treatment.

4.1.6. Auditing and developing practices

At the time when the compliance inspections were performed, the county councils had no model for how audits should be performed. There was also a lack of set criteria for such audits. This situation was a national predicament that led to the Swedish Radiation Safety Authority taking the decision in June 2009 to appoint a working

party whose purpose is to develop and propose a national model for clinical audits of radiotherapy work. Radiotherapy was chosen as an area with specific parameters because this practice is well defined and conducted at a small number of clinics. The model is to serve as support for ongoing development and improvement work at each radiotherapy department and to provide opportunities for improved efficiency. Its purpose is to achieve a level of national coordination, a situation that also has the potential to promote research in the field. This work is in its final phase.

4.1.7. Managing deviations

From the compliance inspections, the Authority has drawn the conclusion that virtually all the county councils were deficient in their management of deviations of radiation safety significance. First and foremost, there was a lack of routines and guidelines for managing, investigating and dealing with deviations. Often, there was also a lack of assessment criteria and criteria defining when a deviation is to be reported to the Authority; also, a lack of guidelines defining which staff functions are to take part in investigations into different kinds of events. In many cases, the relevant staff also lacked training in risk and event analysis. This led to a situation where relevant action was not always taken and there was an elevated risk of incidents reoccurring.

The Swedish Radiation Safety Authority has also reviewed the incidents reported to it and is of the view that relevant events were reported. The number of events reported nevertheless varies considerably between the hospitals, leading to the Authority associating greater likelihood to certain hospitals underreporting events and lesser likelihood to other hospitals overreporting events.

In the international ROSIS project [5], for instance, 101 radiotherapy departments having a total of 343 treatment machines have voluntarily reported incidents to an Internet database. During a period of just over five years, 1,074 incidents were reported, which is around three incidents per treatment machine. There are currently more than 60 treatment machines in Sweden. If we hypothesise that Sweden has the same number of incidents per treatment machine, then 180 incidents would have been reported over a five year period. However, between 2005 and 2010, only 18 incidents were reported to the Swedish Radiation Safety Authority.

4.1.8. Protection of patients

All the county councils had systems for measuring radiation doses, but nevertheless failed to fully meet the requirements.

Radiation doses to patients from examinations

Generally speaking, all the county councils had methods for measuring and recording radiation doses.

The existing systems for recording the estimated radiation dose to patients from X-ray examinations varied in terms of their quality. One example of an effective na-

tionally coordinated system is SCAAR, a Swedish angiography and angioplasty registry for interventional cardiology. All the county councils in question recorded patients' estimated radiation doses in the registry. Deficiencies were nevertheless shown in all the practices using fluoroscopic X-ray imaging procedures in connection with invasive procedures. For example, six out of the nine county councils had no systems for compiling and analysing patients' radiation doses relative to the operators' working procedures.

One of the explanations behind the deficiencies when recording radiation doses to patients was ineffective registration systems, where it was often difficult to enter as well as retrieve data. With no collective record of information nor an analysis of the operators' working procedures, it was not possible to identify individual operators who used the equipment incorrectly, thus causing unnecessarily high radiation doses.

None of the county councils that underwent the inspections fulfilled the requirements on measures to reduce doses. Either the protocols lacked instructions for these measures, or the staff failed to comply with the relevant method descriptions.

Radiation doses to patients from therapy

All the county councils had deficiencies in parts of their routines for ensuring that the distributed radiation dose corresponds to the planned dose. There were mainly deficiencies in verifying the individual dose to patients when new advanced radiotherapy techniques were used.

4.1.9. Protection of staff

The main group of people who receive the highest radiation doses in medical services is individuals working with interventional radiology and unsealed sources in nuclear medicine. Staff working with Positron Emissions Tomography (PET) risk receiving high radiation doses to their hands as they administer radioactive solutions. Staff working in practices using fluoroscopy equipment in connection with different kinds of invasive procedures risk receiving high radiation doses to the lens of the eye. High radiation doses to the eye give rise to cataracts. Studies presented by the ICRP [6] show that the lens of the eye is much more sensitive to radiation than previously thought.

Five out of the nine county councils had not performed radiation dose measurements on hands, forearms, feet, ankles and eyes, implying that these county councils could not verify that dose limits were not exceeded. This also implied that these organisations to some extent lacked knowledge about the radiation doses received by their staff, so they could not minimise the risk of receiving serious occupational injuries caused by radiation.

A prerequisite for optimisation of radiation doses to staff is a risk analysis of occupational situations and working procedures that among other things leads to categorisation of all staff working in practices involving ionising radiation. Eight out of the nine county councils had deficiencies in their system for categorisation of staff. As a consequence, incorrect measures are taken and the wrong decisions are made when optimising staff radiation doses.

4.1.10. Protection of family members and supporting persons

Two out of the nine county councils had deficiencies in their routines for radiation protection measures to be observed on the part of family members and supporting persons. These deficiencies were found in X-ray practices.

5. Risk evaluation from the perspective of radiation safety

The level of severity of these deficiencies when it comes to health care depends on the radiation dose to the patients or staff, in addition to the number of individuals who are exposed to the radiation. Figures 2 and 3 illustrate the risk analysis model used by the Swedish Radiation Safety Authority when it evaluates radiation safety between practices. In the practices assessed as having a major impact on radiation safety, the Authority has determined that there is a very high risk of injury or, alternatively, a low risk of injury depending on either a high or low level of compliance. In the practices assessed as having a small impact on radiation safety, the Authority's risk evaluation shows only a high relative risk of injury or, alternatively, a very low relative risk of injury depending on either a high or low level of compliance with legislation.

Since the Swedish Radiation Safety Authority has found that the county councils that underwent the inspections generally did not comply with the requirements in the form of legislation and regulations, all the areas end up in the lower quadrants of the risk analysis model. This means that these practices are conducted at a high or very high risk of injury in relation to each other.

As far as concerns patients, the Swedish Radiation Safety Authority is of the view that radiotherapy is associated with the highest relative risk because the licensees' level of compliance is low.

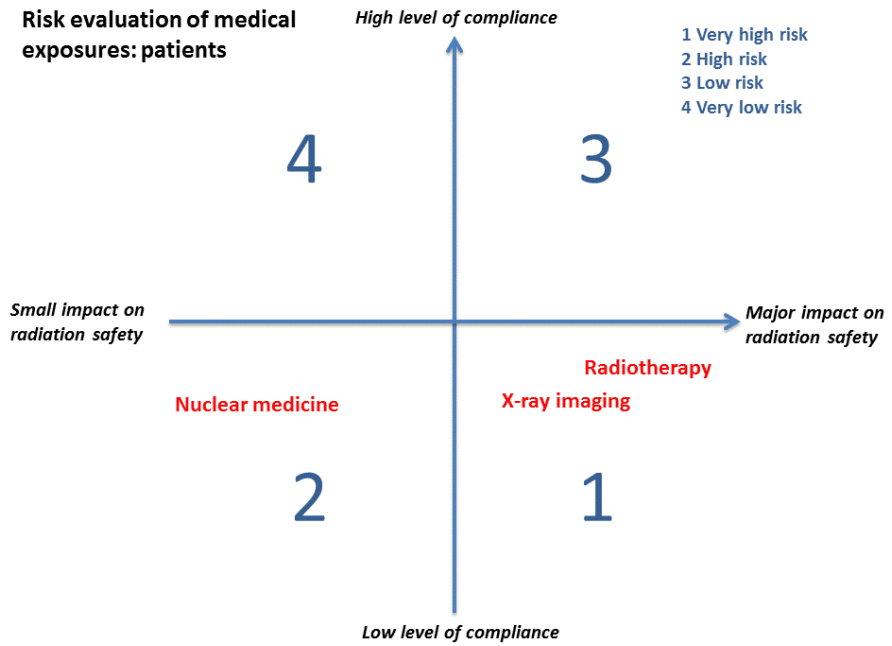

Figure 2. Risk analysis model for evaluating radiation safety on the part of patients in health and medical services.

- Patients undergoing radiotherapy receive very high radiation doses and risk acute injuries unless the treatment is optimised. What's more, patients risk delayed injuries in the form of radiation-induced cancer. Each year, 25,500 patients undergo radiotherapy, meaning that radiation treatment on the whole is assessed as having a major impact on radiation safety, while also being associated with a very high level of risk if the requirements are not complied with.

- Patients undergoing X-ray examinations or invasive procedures using fluoroscopy equipment risk receiving relatively high radiation doses unless the radiation exposure is optimised. Each year, there are 5,400,000 instances of this kind of irradiation, which poses a risk to the population of delayed injuries in the form of radiation-induced cancer. There is also a risk that patients undergoing invasive procedures using fluoroscopy equipment will receive very high radiation doses and thus acute radiation injuries in the form of reddened skin and sores that are slow to heal. Altogether, X-ray examinations are assessed as having a major impact on radiation safety, while also being associated with a very high level of risk if the requirements are not complied with.

- Patients undergoing nuclear medicine examinations and treatments risk receiving relatively high radiation doses unless the radiation exposure is optimised. Each year, only 100,000 examinations and 2,500 treatments are performed. Altogether, it is assessed that nuclear medicine has a relatively small impact on radiation safety and is consequently only associated with a high level of risk if the requirements are not complied with.

As far as concerns staff, the Swedish Radiation Safety Authority is of the view that X-ray examinations are associated with the highest relative level of risk because the licensees' level of compliance is low. This is particularly the case for staff taking part in invasive procedures using fluoroscopy equipment.

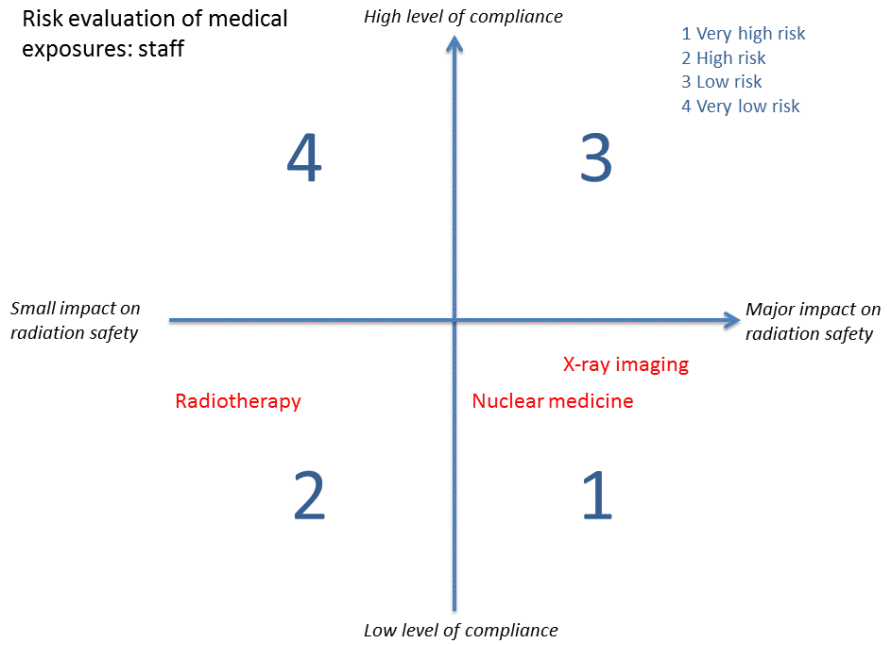

Figure 3. Risk analysis model for evaluating radiation safety on the part of staff in health and medical services.

- Staff working with radiotherapy are not present in the room for treatment during the radiation exposure. On the other hand, they handle low-level sources of radioactivity in connection with a small number of treatments. Altogether, they risk receiving a relatively low radiation dose. For this reason, it is assessed that radiotherapy has a relatively small impact on radiation safety and is only associated with a high level of risk if the requirements are not complied with.

- Staff performing X-ray examinations are normally not present in the treatment room during the radiation exposure and risk receiving a relatively low radiation dose. On the other hand, staff taking part in invasive procedures using fluoroscopy equipment risk receiving high or very high radiation doses to their eyes and fingers, which can lead to permanent eye damage (cloudy lens) or hair loss on their fingers and hands unless the radiation exposure is optimised. Altogether, X-ray imaging is assessed as having a major impact on radiation safety, while also being associated with a very high level of risk if the requirements are not complied with.

- Staff working with nuclear medicine examinations and radiation treatment risk receiving high radiation doses and thus acute injuries from incorrect handling of radioactive material. Nuclear medicine is assessed to have a relatively large impact on radiation safety and is consequently associated with a very high level of risk if the requirements are not complied with.

On the other hand, if the requirements imposed on these practices are complied with, medical exposures can be performed with a low or very low level of risk.

6. Conclusions

The Swedish Radiation Safety Authority has drawn the conclusion that the county councils' practices involving ionising radiation generally demonstrated major shortcomings in their compliance:

- None of the county councils complied with the requirements imposed on the organisation, control, management and follow-ups of radiation safety work. This suggests a lack of awareness about the importance of quality management systems among county council decision-makers. This situation has led to non-existent quality management systems or major shortcomings in the existing quality management systems of all the county councils that underwent the inspections.

- The county councils had staff with the relevant basic education in the form of radiologists, oncologists, radiographers, authorised medical physicists and other members of staff, implying that the prerequisites are in place for these county councils to provide radiation-safe health and medical care. Here, however, one assumption is that the county councils' senior management must clearly define mandates and roles in the organisation. For instance, they must ensure that suitable individuals are appointed as practitioners and actively take part in assessing justification and systematic optimisation work in all the practices using ionising radiation. They must also ensure that the staff have the practical and theoretical training needed for performing their tasks.

- Generally, there were major shortcomings in local training on methods, equipment and radiation protection, which is surprising since training of staff serves as the foundation of safe medical exposures.

Due to the low level of compliance with legislation, the county councils could not ensure that medical exposures were justified and optimised, nor could they ensure that medical exposures were performed in accordance with the established working procedures. The compliance inspections performed in 2011, but not yet compiled, also show the same deficiencies.

Altogether, this implies that health and medical services have deficiencies in the area of radiation safety that could lead to serious consequences for patients and staff.

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Definitions

Audit	A systematic evaluation of the clinical radiological procedures and routines in relation to established working procedures for good care, and which, if necessary, bring about modification of, or the implementation of, new working methods with the aim of raising the standard of the practice and the quality of the care results.
Optimisation	The process of, based on given economic aspects and aspects in society: a) adapting the extent of the examination and the radiation dose to the individual undergoing medical exposure for diagnostic purposes so that the radiation dose is as low as reasonably achievable, while at the same time ensuring that the desired diagnostic information is received, or b) adjusting the radiation dose to the individual undergoing medical exposure for therapeutic purposes so that the radiation dose achieves the intended therapeutic effect, while keeping the radiation dose to healthy tissue as low as reasonably achievable, or c) taking into account that the radiation dose to a foetus must be considered as part of planning and performing an examination or treatment of the mother-to-be so that the dose to the foetus is as low as reasonably achievable, and d) while at the same time observing the kinds of procedures resulting in the occupational radiation doses and doses to the general public being as low as reasonably achievable.
Justification	a) An assessment according to which a medical exposure gives a benefit to the patient, having taken into account the diagnostic information or therapeutic results, that outweighs the detriment estimated from the radiation exposure, while also taking into account the effectiveness, advantages and risks of existing alternative methods implying a lower radiation dose or that do not at all use ionising radiation, or b) an assessment according to which medical exposure of human volunteers gives a benefit for medical or biomedical research that outweighs the detriment estimated to be caused by the radiation exposure, or c) an assessment according to which exposure to a living human being in a legal investigation, or in an insurance context, gives a benefit to the individual or society that outweighs the detriment estimated from the radiation expo-

	sure, or d) an assessment according to which exposure to a family member or other individual who is assisting and supporting a patient during the exposure gives a total benefit to the patient and family member or supporting person that outweighs the detriment estimated from the radiation exposure.
Practitioner	A function held by an individual with the prescribed competence and who, in their field, exercises a comprehensive influence over assessments of justification, optimisation, working procedures, staff competence, co-operation with representatives of other specialist areas, as well as clinical evaluations of the results.
Medical exposure	Irradiation using ionising radiation of: 1. Patients for diagnostic or therapeutic purposes 2. Individuals as part of occupational health surveillance 3. Individuals in screening programmes 4. Individuals participating in research programmes 5. Living individuals in legal investigations 6. Individuals in an insurance context

Abbreviations

mSv	millisievert (a sievert is a unit for the radiation dose received)
manSv	manSievert, a unit for collective dose

Appendix

The county councils' practices involving ionising radiation were inspected on the basis of their respective organisations, control and management, the resources available for their work, such as staff, equipment and premises, as well as their operations from the perspectives of patients, staff and the general public. The following sections provide a summary account of the deficiencies identified following the compliance inspections performed within nine county councils between 2005 and 2010 [7].

Organisation, control and management

Requirements

The licensee must organise the radiation safety work and adapt it to the nature and scope of the work activities. A description of how this work is organised is to be documented in the form of an organisation scheme that must be kept up-to-date. This scheme must at least include the following information:

- the forms of co-operation between the licensee, hospital senior management, director, practitioners, medical physicists and other relevant staff,
- how the tasks relating to radiation safety are allocated, for instance the arrangements for training of staff in radiation protection, methods and handling of equipment, and
- the medical physicist whose task it is to serve as the point of contact with the Swedish Radiation Safety Authority.

Are the requirements fulfilled?

All nine county councils that underwent the inspections were criticised by the Authority about the way in which their radiation safety work was organised, controlled and/or followed up. Some of this criticism concerned:

- the documented organisation scheme, which was often outdated and not adapted to the practices,
- the fact that key roles in the organisational structure were omitted from the description of the radiation protection organisation, despite these persons' significant de facto role in radiation safety work (e.g. new supervisory levels had been added or removed),
- the allocation of responsibility and authority: there were cases of individuals having an allocated responsibility for tasks, but without the authority required for performing these tasks.

The requirement on an appointed contact person was fulfilled by all the county councils that underwent the inspections.

Quality assurance

Requirements

The licensee must ensure that a quality assurance system has been set up and documented in a quality assurance manual. The requirements stipulate that:

- each piece of equipment must have accompanying protocols covering how all routine examinations and treatments are to be performed,
- regular audits of the practice are to be performed.

Are the requirements fulfilled?

Eight out of the nine county councils lacked a cross-cutting and comprehensive quality assurance manual. The level of the existing quality assurance systems varied considerably between the county councils/organisations and between work activities and practices in the same organisation. There were seldom any shared guidelines on the design and formulation of documents, nor who was to give final approval to the documents or their period of validity. There was often no list available showing the existing documents or records in the organisation. Also, there were seldom any guidelines on document audits.

Audits

Requirements

Regular audits of the practice are to be performed. On each occasion that new findings are made available, existing methods or applications of medical exposures are to be reassessed for their efficiency or effectiveness with the aim of raising the practice's level of quality and the care results.

Are the requirements fulfilled?

None of the county councils that underwent the inspections had performed any kind of systematic clinical audit of the radiological methods. However, certain practices audited their methods as part of separate projects such as clinical studies. To some extent, all the county councils performed clinical audits of X-ray examinations and nuclear medicine examinations because they fulfilled the requirement on diagnostic reference levels and standard doses.

Managing deviations

Introduction

Deviations occur every day in medical services. In order to prevent these incidents or nonconformities from reoccurring, a system must be in place for managing, investigating and dealing with these deviations.

Requirements

Incidents of significance for radiation safety must be reported by the contact person to the Swedish Radiation Safety Authority. Such report shall provide a description

of the event and the measures taken in order to prevent a reoccurrence. Routines must be in place for rectifying the situation.

Are the requirements fulfilled?

Seven out of the nine county councils that underwent the inspections were criticised for their deviation management. There was often a lack of routines and guidelines for managing a deviation involving radiation, in addition to criteria for the point in time for reporting to the Swedish Radiation Safety Authority. During these compliance inspections, the Authority identified several events involving radiation that had not been reported as required.

Statistics

The degree to which events were reported varied between the county councils, in a particular county council, between individual hospitals and between practices at the same hospital.

The number of incidents reported to the former and present regulatory authorities in Sweden during the period 2000–2010 increased over these years. Between 2004 and 2005, there was a marked increase in reporting after the former regulatory authority, SSI (the Swedish Radiation Protection Authority), pointed out that the frequency of reporting was low.

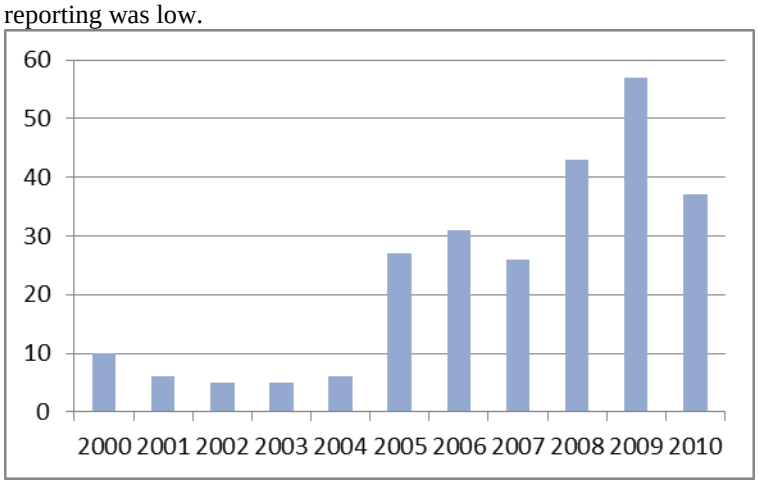

Figure 1. The number of incidents reported to the former and present regulatory authorities in Sweden (Swedish Radiation Safety Authority) during the period 2000–2010.

A total of 221 incidents were reported to the former and present regulatory authorities in Sweden (Swedish Radiation Safety Authority) between January 2005 and December 2010. Of these events, 169 resulted in a radiation dose to patients that was too high or too low; five events exposed staff to radiation, with:

- 64 per cent having been reported from X-ray practices,
- 8 per cent reported from radiotherapy, and
- 28 per cent reported from nuclear medicine.

Resources

Competence and staffing

Introduction

All staff working with medical exposures are required to possess the formal and practical skills necessary to ensure that a specific practice can be conducted in an environment offering good radiation safety. ‘Competence’ refers to one’s capability to correctly perform a task.

- ‘Formal competence’ refers to the skills learned by an individual through formal education and training and that can be documented in the form of a licence, degree, certificate or diploma.
- ‘Practical skills’ refers to the hands-on skills possessed by an individual and which he or she can consequently utilise in order to solve a problem or perform a task.

Practical skills set the standard for one’s daily work.

The responsibility for organising training programmes

Requirements

The Radiation Protection Act stipulates that a licensee has the ultimate responsibility for ensuring that its staff have the appropriate skills. Below this level, the supervisor of the relevant staff is to–together with the medical physicists and the individuals who are the practitioners–be in charge of ensuring that the staff have the competence that is needed and undergo continuing education.

A description of the arrangements for training in radiation protection, methods and handling of equipment must serve as part of a licensee’s documentation on the organisation of radiation safety work. This documentation must clearly state the steps of training required for different categories of staff as qualifications to perform a certain task.

Are the requirements fulfilled?

All the county councils that underwent the inspections were criticised for how their training for medical staff was organised. Here, the main areas were programmes for introductory training in radiation protection and handling of equipment for new members of staff. There was a lack of routines and programmes for:

- how the training should be held, and
- the content of training courses.

Following up and accounting for training programmes

Requirements

The licensee must ensure that all staff taking part in medical exposures have the theoretical and practical skills needed.

It must be possible for the respective staff member to undersign a record as confirmation of completed training programmes to demonstrate that they have completed courses in safety routines and other course modules.

Are the requirements fulfilled?

All the county councils had deficiencies in their work on ensuring that the staff had received the planned training. No systematic follow-ups took place to ensure that all staff had received the intended training. There was also a lack of signed course certificates from completed course modules.

A large proportion of the physicians who took part in practices involving ionising radiation lacked training in the field, particularly in departments using X-ray imaging outside the X-ray departments.

Radiation protection committee

Introduction

The committee's main task is to supervise radiation safety on the part of patients and individuals participating in research programmes.
Organisations conducting relatively small practices that do not have a radiation protection committee can request the assistance of the nearest local radiation protection committee or SSM for assessments of research projects.

Requirements

If the practice is conducted at several clinics, a radiation protection committee is required. If the practice is relatively extensive, the committee may be divided into smaller, separate groups. The committee's tasks include:

- striving to ensure that the practice fulfils the requirements imposed,
- serving as the licensee's body of advisory experts in aspects of radiation protection relating to patient safety,
- providing advice about new methods of examination or treatment, also about new equipment, and
- assessing research projects in which human volunteers are exposed to radiation and assisting the ethics committee as part of such assessments.

Members of the radiation protection committee shall include:

- medical physicists,
- the individuals appointed as the practitioners, and
- representatives of other practices as determined by the licensee.

Are the requirements fulfilled?

All the county councils that underwent the inspections had a radiation protection committee that largely worked with the requisite tasks, although in some cases the assignments and tasks of the committee needed to be defined more clearly. Minutes were available from meetings of the radiation protection committee confirming that the committee was active. However, the licensees seldom read these minutes.

Four of the nine county councils did not fulfil the requirements because:

- the individuals appointed as practitioners were not members of the radiation protection committee, and
- not all the practices using ionising radiation were represented in the committee.

Medical physicists

Introduction

SSM requires authorised medical physicists to take part in medical practices involving ionising radiation. All the county councils have indeed set up an organisation comprising several authorised medical physicists specialised in the fields of X-ray imaging, radiotherapy and nuclear medicine. Most of these medical physicists are involved in clinical work.

Requirements

Besides the requirement for a practice to include at least one medical physicist, there must also be an appointed medical physicist whose task is to serve as the licensee's expert in matters related to radiation safety.

Licensees must ensure that this qualified expert has the authority and resources needed for achieving a satisfactory level of radiation safety.

Generally, a medical physicist is to:

- have good insight into the organisation's work,
- be involved in planning and implementing quality assurance programmes covering procedures as well as equipment,
- be responsible for evaluating new examination and treatment methods from the point of view of radiation safety,
- be responsible for the way in which checks of equipment should be performed,
- take part in investigations into incidents involving radiation,
- be involved when procuring new equipment,
- plan and check radiation safety in connection with new construction and refurbishing or rebuilding of premises,
- ensure that routines are in place for monitoring occupational radiation doses, and
- together with staff supervisors and the practitioners, design and hold training programmes needed from the point of view of radiation safety.

There are additional specific requirements pertaining to medical physicists depending on the kind of practice.

Are the requirements fulfilled?

With one exception, all the county councils that underwent the inspections fulfilled the formal requirement imposed on the licensee to have a medical physicist with expert knowledge in aspects of radiation safety. In practice, however, the licensees and the appointed experts lacked a dialogue on these aspects.

Four out of the nine county councils did not fulfil all the requirements imposed on the role of the medical physicist. The tasks, responsibilities and authority of the medical physicist were not clearly defined.

A few of the county councils lacked authorised medical physicists with the right expertise for the field in which the respective practice belonged.

Practitioners

Requirements

The Swedish Radiation Safety Authority requires the presence of a physician who is the practitioner for the purpose of maintaining radiation safety since it cannot be assumed that the director has sufficient competence for these kinds of tasks.

Besides the required individuals appointed as practitioners ('RLF'), another requirement stipulates that these persons must be physicians with specialist expertise in the relevant practice.

Physicians who are practitioners are required to:

- have an overall influence on the radiological work,
- in consultation with medical physicists, actively develop working methods, ensure that suitable equipment is used in the practice, as well as to, in consultation with medical physicists and supervisors, ensure that the staff have the competence needed for their work,
- ensure that an assessment is conducted so that examinations and treatments are justified, and
- be a member of the radiation protection committee.

Are the requirements fulfilled?

Seven of the nine county councils did not fulfil the requirements imposed on the practitioners. The following deficiencies were identified:

- A common problem was that no one had been appointed.
- Occasionally the person appointed was unaware of their having been appointed.
- It was unclear whose responsibility it was to appoint the 'RLF' (practitioner).
- None of the formal decisions had been documented.

Of the individual practitioners, nearly all of them had the requisite formal competence. Only one county council did not fulfil this requirement.

There were deficiencies in how the tasks were performed. A common problem was that tasks, responsibilities and authority on the part of the practitioner were neither specified nor communicated. Often, insufficient time had been reserved for performance of the tasks. Deficiencies observed included the following:

- This function was neither known to, nor utilised by, the directors running practices involving radiation, especially not in external areas such as surgery, urology and orthopaedics.
- The tasks to be performed by the practitioner in collaboration with medical physicists were not performed by this function in several county councils.
- Often, the practitioner was not a member of the radiation protection committee.

Equipment and apparatus

Introduction

All medical equipment and apparatus must be in compliance with the Medical Products Agency's regulations and have the CE mark. The Swedish Radiation Safety Authority imposes requirements on performance and inspections of equipment. The kinds of equipment subject to the Authority's regulations include technical devices which are capable of generating radiation or which contain a radioactive substance, instruments that can measure radiation, sources of radioactivity used for therapy or calibration work, computers (hardware and software) used for diagnostics or therapy, as well as radiation protection items such as lead aprons and ventilation equipment in laboratories.

Procurement of equipment

Requirements

Medical physicists must take part in procurement processes and work together with practitioners to ensure that aspects of radiation safety are taken into account and that suitable equipment is used in the practice. Additional requirements are imposed on the design of various kinds of equipment. Procurement of new equipment means ensuring that these requirements are fulfilled.

Are the requirements fulfilled?

Five of the nine county councils did not fulfil the requirements on procurement of equipment. Routines needed to be modified in order to ensure that aspects of radiation safety were taken into account during procurement processes. Neither medical physicists nor practitioners took part in the procurement process to the extent necessary.

Quality control measures, service and maintenance

Requirements

Medical physicists are responsible for the way in which the prescribed quality control measures are performed to ensure that the equipment is safe. A measurement protocol must be drawn up and signed after each quality control measure.

- Acceptance testing of the equipment must be performed before being first used clinically. Acceptance testing must, as a minimum, encompass all parameters and functions affecting image quality and radiation dose. Output values intended to be used for comparison purposes during quality control measures are to be produced in connection with acceptance testing.
- Checks of the functions must be performed regularly and following all maintenance that can have an impact on equipment properties from the point of view of radiation safety.
- Each piece of radiation equipment in the therapy practice is to be subject to an independent and external quality control measure that will determine the dose in the radiation field.

Another requirement is that reference instruments must be regularly calibrated at a national metrology institute or the equivalent.

Are the requirements fulfilled?

None of the county councils fulfilled all the requirements imposed on quality control measures, service and maintenance. The following deficiencies were observed:

- Acceptance tests of all equipment emitting ionising radiation were not performed by several county councils. There was also a lack of routines for conducting acceptance tests.
- All the county councils had routines for quality control measures, though not all equipment was subject to quality control measures at the prescribed intervals.
- Quality control measures following completed service were not always performed before the piece of equipment was once again taken into clinical use.

Premises and rooms

Introduction

Examples of premises and rooms used in practices involving radiation, and which are subject to requirements imposed by SSM, include examination rooms at X-ray departments, treatment rooms for radiotherapy, as well as laboratories, storage rooms, waste rooms for radioactive material and waiting rooms at nuclear medicine departments.

Categorisation of premises and rooms

Requirements

Premises/rooms used for diagnostics or therapy involving ionising radiation must be categorised if the staff risk receiving radiation doses exceeding the specified levels. It is the responsibility of the licensee to ensure that the premises and rooms are correctly categorised:

- Premises/rooms where the staff might receive radiation doses exceeding a whole body dose of 6 mSv, a dose to the eye of 45 mSv or dose to the skin of 150 mSv are to be classified as controlled areas.
- Premises/rooms where the staff might receive radiation doses exceeding a whole body dose of 1 mSv, a dose to the eye of 15 mSv or dose to the skin of 50 mSv are to be classified as supervised areas.

Are the requirements fulfilled?

None of the county councils that underwent the inspections fulfilled the requirements on categorisation of premises/rooms used for X-ray and nuclear medicine practices. There was a lack of routines and criteria for categorisation. Several workplaces where radiation was used were also not categorised.

All the county councils fulfilled the requirements imposed on premises and rooms used for radiotherapy.

Radiation shield system

Premises/rooms must be designed so as to minimise the risk of people being exposed to radiation by mistake.

Requirements

It must be possible for people to be present without safety instructions outside premises and rooms where radiation is used. This implies their having been built so that it is unlikely for the effective radiation dose to exceed 0.1 mSv per year for persons present outside the premises/rooms in spaces not classified as controlled or supervised areas. Particular requirements apply to premises and rooms where radioactive solutions are kept.

Documentation about the radiation shield system must be available and calculations and measurements must be retained. Authorised medical physicists are responsible for planning and checking to ensure that the relevant premises and rooms are radiation safe.

Are the requirements fulfilled?

Six out of the nine county councils did not fulfil the requirements on ensuring that the premises/rooms were designed so that the dose limit is not exceeded.

The radiation shield system in radiotherapy rooms was nonetheless often well documented and fulfilled the requirements imposed.

The design of premises and rooms

Premises and rooms where radiation is used must be divided into categories, a *controlled* or *supervised area*, in order to protect staff from high radiation doses. The premises/rooms must be delineated or guarded and marked using signs.

Requirements

Categorised premises and rooms must be marked with signs. A controlled area shall be delineated and access to it restricted to authorised persons only:

- During X-ray examinations, it must be possible to observe the patient from the equipment's control area.
- Premises/rooms in which work involving unsealed sources takes place must have floor, wall and work surfaces of materials that are straightforward to decontaminate. It must also be possible to change working clothes, wash hands and perform contamination checks.
- Laboratories in which radioactive pharmaceuticals are manufactured/prepared must be underpressurised compared with surrounding spaces and it must not be possible to open the windows without a key.
- A particular requirement for radiotherapy is that a safety system must be in place to prevent unauthorised access to the treatment rooms. The premises/rooms must also have control devices for ensuring that the spaces are checked prior to the radiation exposure starting so that no one apart from the patient is present in the treatment room. Outside treatment rooms, signals are to sound when irradiation is in progress.
- Purpose-built premises/rooms must be available for handling and storage of radioactive sources for brachytherapy.

Are the requirements fulfilled?

Most of the requirements were fulfilled by all the county councils. The following deficiencies were nevertheless observed:

- Five county councils received criticism because their signage of premises/rooms did not fulfil the requirements.
- One county council was issued an injunction concerning locking premises/rooms in which sources of radioactivity were kept.
- Two county councils were issued injunctions concerning the installation of a button for visual assurance in their radiation treatment rooms.

Premises and rooms: instructions for staff

Requirements

- For each controlled area, working instructions must be available in writing describing how the work is to be performed and the protective measures to be taken by those working in the area.
- All supervised areas shall have working instructions drawn up in writing.

The instructions shall be adapted to the nature of the work and radiation sources in question and be available at the workplaces.

Are the requirements fulfilled?

Five out of the nine county councils were issued injunctions on drawing up working instructions for performing work in controlled and supervised areas. In general, however, the safety routines were well documented as far as concerns working procedures in rooms for radiotherapy.

Practices

Radiation protection of patients

Introduction

Patients' therapy and examinations are to be undertaken while ensuring radiation safety. There are no dose limits for patients. On the other hand, there are reference values, i.e. diagnostic reference levels, that serve as an indicator of the level of radiation safety for certain common kinds of examinations. SSM imposes requirements on documented and approved working procedures to ensure that treatments and examinations are performed in accordance with quality assured procedures and that special considerations are given to children and pregnant patients.

Protocols

Requirements

All pieces of equipment are to be supplied with written protocols on how to perform all routine examinations or therapy to be performed there:

- Protocols for examinations must contain information about measures to reduce doses, such as gonad protection and compression, for example. Medical physicists are in charge of evaluating new examinations from a radiation protection point of view.
- It must be evident for all treatment methods as part of radiotherapy who is responsible for each individual step of the therapy. The protocols must also make it clear that key parameters of treatment are to be verified by means of two independent methods, or by two persons independently of each other.

Are the requirements fulfilled?

None of the county councils that underwent the inspections fulfilled the requirements on protocols. Common deficiencies included:

- not all pieces of equipment had been supplied with protocols,
- existing protocols were incomplete,
- the staff did not adhere to protocols, or
- existing protocols lacked instructions on procedures to reduce doses.

One of the outcomes of regulatory supervision showed that the protocols in some cases were only adhered to in 25 per cent of the examinations.

Pregnant women

Requirements

In connection with an examination or treatment of women of fertile age, the referring physician and the physician who is to take a decision on medical exposure must investigate whether the female patient is pregnant. In the event of pregnancy, or if the possibility cannot be ruled out, special efforts shall be made to protect the foetus.

Are the requirements fulfilled?

Four out of the nine county councils did not fulfil the requirements imposed on protecting the foetus. A large proportion of women of reproductive capacity were not asked about the possibility of their being pregnant prior to examining areas close to a possible foetus:

- Instructions were omitted from the protocols,
- the staff did not adhere to existing routines.

Examinations of children

Requirements

Examinations of children must be performed while using appropriate measures to reduce doses. This must be documented in protocols.

Are the requirements fulfilled?

Two out of the nine county councils were issued injunctions on developing particular routines for examinations using appropriate measures to reduce doses to children.

Radiation doses to patients

Requirements

All radiation exposure must be optimised. This for instance implies that:

- diagnostics are to involve measuring doses to patients,
- if the diagnostic standard dose exceeds the diagnostic reference level during X-ray examinations, the cause must be investigated and measures taken to reduce the dose,
- journals of fluoroscopy are to be kept for invasive procedures and fluoroscopy and an individual annual compilation of fluoroscopy exposure times is to be reported back to all the relevant directors and operators,
- criteria must be defined for identifying patients who might risk receiving an acute radiation injury from fluoroscopy,

- before radiotherapy begins, individual dose planning must be conducted for each patient; also, physicians and medical physicists must both sign the treatment protocol, and
- external radiotherapy must involve verifying the individual patient dose by conducting measurements the first time a new radiation field is applied.

Are the requirements fulfilled?

All nine of the county councils fulfilled the requirements on measuring diagnostic standard doses and individual dose planning. Few examinations, including computed tomography, exceeded the diagnostic reference levels.

In nuclear medicine, all the county councils had routines for measuring and recording all levels of activity administered and they had particular routines for adapting levels of activity for administering to children. For conventional treatment techniques, all the county councils fulfilled the requirement on verifying the individual patient dose through measurements. However, there were deficiencies in the way measurements were performed in connection with more advanced techniques such as Intensity-Modulated Radiation Therapy (IMRT) and Image Guided Radiation Therapy (IGRT).

Six out of the nine county councils were issued injunctions on developing routines for compiling, analysing and evaluating fluoroscopy exposure times on an individual level. This is in addition to all the county councils showing deficiencies in their identification and follow-ups of patients who might have received an acute radiation injury from fluoroscopy. Often, there was a lack of criteria for identification of patients and routines for follow-ups together with referring parties.

Radiation protection of staff

Introduction

The licensee must ensure that all radiation exposure to people is limited as far as reasonably possible. Dose limits for staff working with ionising radiation must not be exceeded.

Categorisation of employees

Requirements

Depending on the maximum level of radiation dose allowed for employees, the licensee must assign each employee to either category A or B:

- A worker shall belong to category A if the likelihood is not negligible that:
    1. the annual effective dose amounts to 6 mSv or more, or
    2. the annual effective dose to the lens of the eye amounts to 45 mSv or more, or
    3. the annual equivalent dose to the hands, forearms, feet, ankles or the skin amounts to 150 mSv or more.
- Workers not belonging to category A shall belong to category B.

Are the requirements fulfilled?

Eight of the nine county councils did not fulfil the requirements due to a lack of:

- a system for categorisation of staff,
- a system to enable verification of staff belonging to the correct category,
- routines for providing information to staff about categorisation and the applicable regulations.

Medical examinations

Requirements

A medical examination shall be conducted before an individual is engaged in a practice in category A. A medical examination must subsequently be conducted no less than once every three years for as long as the individual is engaged in the work. Submitted health declarations are to serve as the basis of periodic health reviews, which must be conducted in interim years when medical examinations are not conducted.

Are the requirements fulfilled?

Four out of the nine county councils were issued injunctions on developing routines so that category A staff continue to undergo medical examinations and submit health declarations in the prescribed intervals.

Monitoring of individual doses

Requirements

Monitoring of individual doses must be performed for all workers belonging to category A. If the work is of a nature implying that particularly high doses can be expected to the lens of the eye, the hands, forearms, feet, ankles or the skin, measurements of these parts of the body shall be performed. If an unexpected change of dose to any worker occurs, the reason must be investigated.

Are the requirements fulfilled?

Five out of the nine county councils did not fulfil the requirements on measuring doses to extremities such as the fingers and eyes of staff belonging to category A. On the other hand, all the county councils performed individual dose monitoring of the torso in accordance with the requirements.

Two county councils were issued an injunction on developing routines for following up and evaluating the results of dose measurements.

Protection equipment

Requirements

The licensee must ensure the availability of protection equipment for use by the workers as necessary. Personal as well as permanent protection equipment is to be checked to ensure its availability and performance a minimum of once per year.

Are the requirements fulfilled?

All nine of the county councils largely fulfilled the requirements imposed on protection equipment. However, one of the county councils was issued an injunction on

developing routines for the way in which personal radiation protection equipment is to be inspected and used.

Pregnant staff

Requirements

The party that conducts the practice must inform female staff of reproductive capacity about:

- the risks that exposure may pose to the foetus in the event of pregnancy, and
- the right to be transferred to work that does not imply exposure to radiation.

If a pregnant woman is not transferred, the work must be planned so that the dose to the foetus does not exceed 1 mSv.

Are the requirements fulfilled?

One of the nine county councils was issued an injunction on preparing a routine for the protection of pregnant staff.

Outside workers

Requirements

The Swedish Radiation Safety Authority's regulation concerning outside workers only applies to category A workers in controlled areas. The same regulations and conditions applying to employees are to be applied to outside workers.

Are the requirements fulfilled?

Two of the nine county councils were issued injunctions on preparing routines for the tasks of outside workers.

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The Swedish Radiation Safety Authority has a comprehensive responsibility to ensure that society is safe from the effects of radiation. The Authority works to achieve radiation safety in a number of areas: nuclear power, medical care as well as commercial products and services. The Authority also works to achieve protection from natural radiation and to increase the level of radiation safety internationally.

The Swedish Radiation Safety Authority works proactively and preventively to protect people and the environment from the harmful effects of radiation, now and in the future. The Authority issues regulations and supervises compliance, while also supporting research, providing training and information, and issuing advice. Often, activities involving radiation require licences issued by the Authority. The Swedish Radiation Safety Authority maintains emergency preparedness around the clock with the aim of limiting the aftermath of radiation accidents and the unintentional spreading of radioactive substances. The Authority participates in international co-operation in order to promote radiation safety and finances projects aiming to raise the level of radiation safety in certain Eastern European countries.

The Authority reports to the Ministry of the Environment and has around 270 employees with competencies in the fields of engineering, natural and behavioural sciences, law, economics and communications. We have received quality, environmental and working environment certification.

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