



Strål
säkerhets
myndigheten

Swedish Radiation Safety Authority

Regulatory framework and inspections in Sweden

MedInspector Workshop 2018

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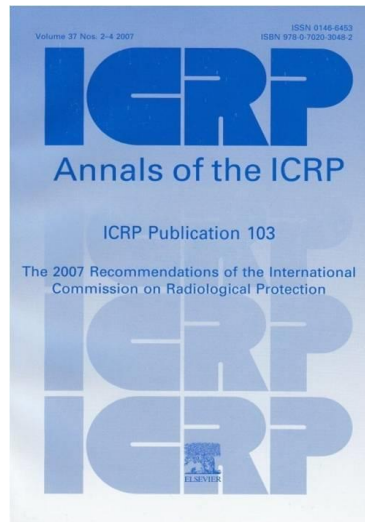
CONTENT

- Transposition of the BSS
- Competence of inspectors
- Inspection Programme
- Inspections finding
- New issues



Transposition of the BSS

Recommendations



EU directive
2013/59 Euratom
(Strålskyddsdirektivet)



National legislation
(medical)

- ➔ Radiation protection Act
- ➔ Radiation protection Ordinance
- ➔ The Higher Education Act
- ➔ Patient Safety Act
- ➔ SSM:s regulations



Practices involving the use of radiation

Radiation protection Act and ordinance

Licensing

General provisions for practices that require licensing

Viss kärnteknisk verksamhet

Industriell radiografering

Medical exposure

Viss veterinärverksamhet

Starka laserpekare

Registration

Anmälningspliktig verksamhet med strålning

- Viss odontologisk röntgendiagnostik
- Viss veterinärverksamhet
- Kabinetröntgen
- Vissa tekniska anordningar
- Vissa slutna strålkällor
- Vissa öppna strålkällor
- Mikrovågstorkning
- Medicinska solarier
- Yrkesmässig handel med strålkällor

Arbetsplatser med förhöjd halt av radon

Kosmetiska solarier

Laser

Exemption and clearance

Exemption and clearance

Hantering av kontaminerad aska

Naturligt förekommande radioaktivt material

Brandvarnare och rökdetektorer med radioaktivt ämne

Bäringskikare, pejlkompass och riktmedel som innehåller tritium

Röntgenutrustningar och slutna strålkällor för undervisningsändamål

Tekniska anordningar i vilka det alstras parasitär röntgenstrålning



SSMFS 20018:5 Medical exposure

1. Definitions
2. General requirements
3. Management
4. Equipment and premises
5. Procedures
6. Limitation of dose
7. Specific requirements for radiology
8. Specific requirements for radiation therapy
9. Specific requirements for nuclear medicine
10. Specific requirements for workers



Transposition of the BSS

- ➔ BSS article 56.1
 - ...target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes
- ➔ SSMFS 2018:5 Medical exposures
 - Chapter 9. Special requirements for nuclear medicine
 - 7 § Each nuclear medicine treatment shall be preceded by a individual adaptation of the radiation dose to the target volume with due consideration to others exposed tissues.



Transposition of the BSS

- ➔ BSS article 58 d) i)
 - in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;
- ➔ SSMFS 2018:5 Medical exposures
 - Chapter 3. Management, 9 §
 - In external radiation therapy, brachytherapy with sealed radioactive sources with high activity and when in other treatments with ionizing radiation, deemed necessary from the radiation protection point of view, a medical physics expert shall be closely involved.



Transposition of the BSS

- ➔ BSS article 61.1
 - Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure. Special attention shall be given to quality assurance programmes and verification of administered activity.
- ➔ SSMFS 2018:5
 - Chapter 4. Equipment and premises 1 §
 - Chapter 5. Procedures 1 §
 - Chapter 9. Specific requirements for nuclear medicine 5 §



Inspections



Competence of inspectors

Training programme

- Radiation protection (RP)
- RP legislation
- Methods for supervision and inspections
- Compliance procedures relating to requirements
- Writing skills
- Interview methods
- Media strategy and training in media skills
- Presentation skills
- Management
- Safety culture



Inspection Programme Health and medical care

1. INTRODUCTION	2
1.1 BACKGROUND AND PURPOSE	2
1.2 THE AREA OF OPERATION	2
2. ANALYSIS	3
2.1. ASSESSING THE NEEDS	3
2.1.1. <i>Results from the risk registry</i>	3
2.1.2. <i>Experience from prior supervision</i>	10
2.1.3. <i>External requirements and commitments</i>	11
2.2. RESOURCES AND COMPETENCE	11
2.3. AIM AND STRATEGY	12
2.3.1. <i>Medical X-ray</i>	13
2.3.2. <i>Odontology X-ray</i>	15
2.3.3. <i>Nuclear Medicine</i>	16
2.3.4. <i>Radiotherapy</i>	18
2.3.5. <i>Magnetic Resonance Imaging</i>	19
2.3.6. <i>Ultrasound</i>	19
2.3.7. <i>High Activity Sealed Sources</i>	20
2.3.8. <i>Radioactive waste in healthcare</i>	20
3. INSPECTION PROGRAMME	21
3.1 INSPECTION PROGRAMME 2016-2018: INSPECTIONS	23
3.2 INSPECTION PROGRAMME 2016-2018: INVESTIGATIONS AND REVIEWS.....	26
4. REFERENCES.....	27
5. APPENDIX	27





Risk analyse nuclear medicine

Non appropriate equipment are purchased and used in clinic

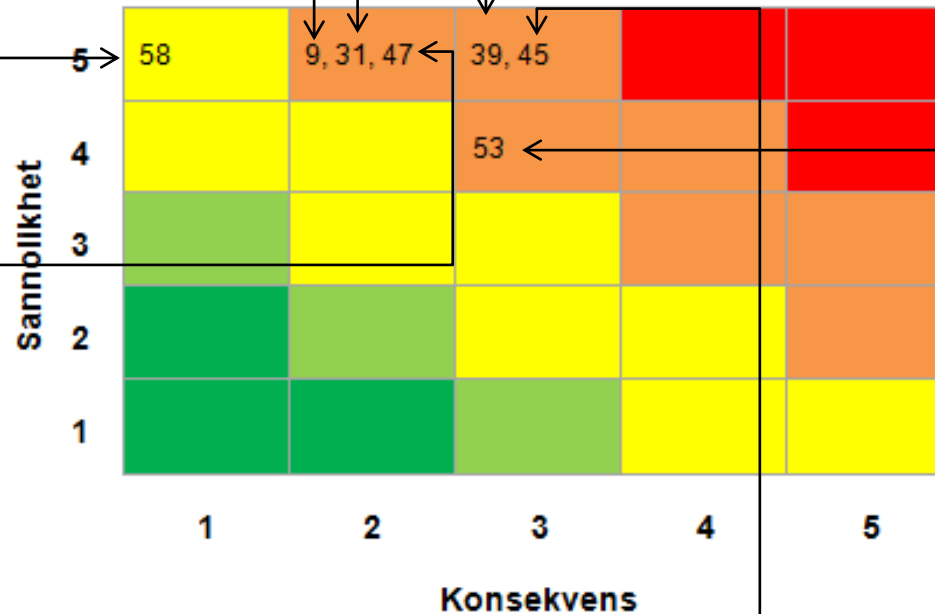
Wrong patient or wrong part of the body is examined

Foetus are exposed to high radiation doses

Unjustified examinations are performed

Personnel with inadequate skills works with radiological equipment

Patients are exposed to higher doses than necessary



Insufficient control after maintenance of equipment



The Inspections of nuclear medicine practices

- Review of documents
- Interview with relevant personnel
- Observations of the clinical work





TABLE 8. INSPECTION PROGRAMME NUCLEAR MEDICINE

LICENSEE	2016	2017	2018	2019	2020	2021
Capio S:t Görans Sjukhus AB		20				10
Danderyds Sjukhus AB	10				20	
Landstinget Blekinge					20	
Landstinget Dalarna	20			10		
Landstinget Gävleborg				20		
Landstinget i Kalmar län	20			10		
Landstinget i Uppsala län	10					20
Landstinget i Värmland					20	
Landstinget Sörmland			10			20
Landstinget Västernorrland					20	
Landstinget Västmanland					20	
Norrbottens läns landsting	20			10		
Region Halland				20		
Region Jämtland Härjedalen						20
Region Jönköpings län				20		
Region Kronoberg					20	
Region Skåne			60			
Region Örebro län	20			10		
Region Östergötland	20			10		
Stockholms läns landsting			40			20
Södersjukhuset AB	20			10		
Västerbottens läns landsting		10				20
Västra Götalandsregionen		40			20	

Enforcements





Inspections finding

- ➔ Lack of management
 - The involvement of physician in the process of optimization has been insufficient.



Summery

- So far no experience from inspections with the new regulations
- A lot of questions from licensees
- New issues
 - optimization of radiation protection of workers



Thank you for your attention!