

SSI FS 2000:7

## The Swedish Radiation Protection Institute's Regulations on Laboratory Work with Unsealed Radioactive Substances;

issued on May 26, 2000.

On the basis of § 7 of the Radiation Protection Ordinance (1988:293), the Swedish Radiation Protection Institute has issued the following regulations.<sup>1</sup>

### Applicability

§ 1 These regulations are applicable to practices with radioactive substances in the form of unsealed sources, performed in laboratory premises and for which a licence according to the Radiation Protection Act (1988:220) is required. The regulations do not apply to practices in nuclear technology.

The regulations in the sections 5, 8 and 9, first clause, are only applicable to extensive practices. The regulations in the sections 12-18 and 24-29 are only applicable to extensive work.

In sub-operations dealing only with the administration of radioactive substances to patients there is no need to meet the regulations in the sections 12-18, 25, 26 and 29.

### Definitions

§ 2 In these regulations the following concepts are used with the meanings specified here.

*Dose-rate:* ambient dose equivalent rate; an operational quantity used in order to estimate the effective equivalent dose when the distribution of the energy and direction of the radiation field is not known for sure,

*extensive work:* a) work with radioactive substances with activity exceeding any of the values given in annex 1 or  
b) work with radioactive substances belonging to radio toxicity Class A, according to annex 2,

*extensive practice:* laboratory work to such an extent that the licence holder's summed up possession of radioactive substances  
a) exceeds 100 gigabecquerel (GBq) or  
b) comprises substances belonging to radio toxicity Class A, according to annex 2 or  
c) exceeds 1 GBq of substances belonging to radio toxicity Class B, according to annex 2 or  
d) exceeds 10 GBq of substances belonging to radio toxicity Class C, according to annex 2,

<sup>1</sup> Cf. Council Directive 96/29/Euratom of May 13, 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, OJ L 159, 29.6.1996, p. 1, (Celex 396L0029).

*unsealed source:* any radioactive substance which neither is  
a) permanently sealed within a non radioactive capsule nor is  
b) firmly bound to a non radioactive solid which prevents spreading  
of the radioactive substance.

### **Organisation and competence**

§ 3 The licence holder shall have established an organisation on radiation protection, which is documented by an organisation chart. The chart shall show how the different tasks are delegated to the qualified expert, the contact person and other persons working with different sub-operations in the practice, as well the persons who have the task to ensure that provided radiation protection measures are taken and that the work on the whole is performed under good radiation protection circumstances. The persons names shall be shown, and the chart shall be kept up to date.

§ 4 The licence holder shall ensure that the persons involved, according to the organisation chart, have sufficient competence on radiation protection and have been granted the necessary authority and resources needed for the radiation protection work.

§ 5 If the practice is extensive, a qualified expert shall be available having such a competence that is described in the Swedish Radiation Protection Institute's General Advice (SSI FS 2000:6) on Competence of Qualified Experts<sup>2</sup>, with respect to parts of concern.

The qualified expert shall be approved by the Swedish Radiation Protection Institute. In order to be approved documentation on the intended expert's competence shall be sent to the Swedish Radiation Protection Institute.

§ 6 The licence holder shall appoint one person as a contact person with the Swedish Radiation Protection Institute. The contact person shall have good knowledge of

1. existing procedures and related radiation hazards,
2. measures to keep the radiation doses to the personnel as low as reasonable achievable and
3. applicable regulations.

At extensive practices the contact person shall have the same degree of competence as a qualified expert. Nothing prevents that it is the same person.

The Swedish Radiation Protection Institute shall be notified of the contact person's name.

§ 7 All personnel in the practice shall get education on radiation protection before work commences. The curriculum shall be adjusted regarding the kind and extent of the work and at least comprise

1. information on the hazards that might be connected to the work,
2. instructions for the radiation protection measures to be taken in the work,
3. the maintenance and the use of protection devices and safety systems.

The personnel shall get education repeatedly at regular intervals, adjusted to the kind and extent of the practice.

<sup>2</sup> The general advice describe the content of the Commission's Communication concerning the implementation of Council Directive 96/29/Euratom, regarding qualified experts, (OJ C 133, April 30 1998).

§ 8 The curriculum for workers having different tasks shall be documented. The time and extent of the given education or information, according to § 7, shall be documented for each worker.

### **Quality assurance**

§ 9 The licence holder shall ensure that a written quality manual is prepared. For extensive practice this manual shall at least include

1. a copy of the licence document as well as further conditions, if any, and applicable regulations,
2. the radiation protection organisation chart,
3. local rules for radiation protection as well as working methods,
4. routines for education of the personnel,
5. the classification of workers and workplaces,<sup>3</sup>
6. instructions for personal dose monitoring
7. program for checks of internal and external contamination, including action levels,
8. description of the routines for calculation of internal doses,
9. routines for calibration and check of radiation protection instruments,
10. routines for purchase,
11. instructions for internal transports and the handling of radioactive waste,
12. action plan in case of unplanned events of significance from a radiation protection point of view,
13. routines for keeping journals and documentation,
14. routines for tidying up and cleaning,
15. routines for audit<sup>4</sup> of the practice.

For non-extensive practices the quality manuals shall be adjusted with respect to the kind and extent of the work.

All personnel concerned shall have knowledge of the quality manual, which also shall be available.

### **Premises and equipment**

#### *General*

§ 10 In planning a new laboratory, attention shall be paid to its location in order to make the internal transports as short and safe as reasonable possible and that places where many persons normally are situated can be avoided.

§ 11 The materials in floors and walls and the design of the fitting up shall be selected in a way that easily allows cleaning.

<sup>3</sup> From the Swedish Radiation Protection Institute's regulations (SSI FS 1998:3) on Categorisation of Workplaces and Workers at Work with Ionising Radiation follow that persons performing extensive work belong to Category A, as a rule. Additional regulations are connected to Category A:

The Swedish Radiation Protection Institute's Regulations (SSI FS 1998:5) on Monitoring and Reporting of Individual Radiation Doses;

The Swedish Radiation Protection Institute's Regulations (SSI FS 1998:6) on Medical Examinations for Work involving Ionising Radiation.

<sup>4</sup> In addition to the requirement of audit from a radiation protection point of view, there are regulations from the Board of Occupational Safety and Health (AFS 1996:6) on audit of the working environment.

*The sections 12-18 only apply to extensive work*

§ 12 The laboratory must only be used for work with radioactive substances. It must only contain materials and equipment needed for the work.

§ 13 The materials of fitting up and equipment shall be selected with the risk of contamination taken into account. The floor, walls and working desks shall be made of non-absorbing material that easily may be decontaminated. Open joints and slits are forbidden.

§ 14 The laboratory shall be provided with an area where it is possible to wash hands, change clothes and perform contamination checks. There must be at least one washstand with taps that can be manoeuvred without the use of hands.

§ 15 The windows in the laboratory must not be able to open without a key or tools.

*Fume-cupboard and ventilation*

§ 16 The laboratory shall be equipped with a fume-cupboard, glove box or equivalent that is able to efficiently take care of air-borne radioactive substances. The ventilation of fume-cupboards and glove boxes shall be of a design that prevents the spread of radioactive substances into other premises. This is most safely achieved with a separate ventilation system. The function of the ventilation shall be checked before each working period.

§ 17 In the laboratory the air pressure shall be lower than in the surrounding premises. The air pressure conditions shall be checked before the practice starts and at regular intervals thereafter, at least twice a year. The results of the checks shall be recorded.

§ 18 Basket funnels, tables and floors shall be strong enough to withstand the weight of necessary radiation shields.

### **Work**

§ 19 The work shall be performed using good laboratory practice<sup>5</sup>.

§ 20 The work shall be planned and performed in such a way that the spread of radioactive substances to the air or surfaces in the laboratory is minimised.

§ 21 There shall be equipment for protection and checks, adjusted to the kind of work, available in the laboratory.

§ 22 The area where work is performed shall be minimised and desks covered with absorbing paper having a plastic underside. Contamination checks of the laboratory, desks and equipment shall be done regularly, at least once a quarter, and whenever there are reasons to suspect contamination. The results shall be documented.

§ 23 At work in the laboratory protective gloves and clothing shall be worn. These items shall be regularly changed.

<sup>5</sup> See the Regulations of the Board of Occupational Safety and Health (AFS 1997:10) on Laboratory Work with Chemicals.

*The sections 24-29 only apply to extensive work*

§ 24 Measurement instruments that are adjusted to the kind of radiation that might be present shall be available. The instruments shall be calibrated and provided with means for simple function checks. The personnel shall be trained to use the instruments.

§ 25 Protective items that have been used in the laboratory must not be used outside the laboratory. Equipment that has to be taken out of the laboratory shall be checked and decontaminated if necessary.

§ 26 The personnel and the working place shall be checked with respect to external contamination after each work.

§ 27 All persons who participate in work where there is a risk of external or internal contamination with radioactive substances shall be checked with respect to internal contamination. The schedule for checks, the type of check and action levels shall be shown by the quality manual.

§ 28 The intended methods for measurements and calculation of internal doses shall be described to the Swedish Radiation Protection Institute. The used methods shall be approved by the authority.

§ 29 The work in the laboratory shall be documented in a logbook in the laboratory. In the logbook shall be noted

1. nuclide and activity,
2. the object of the work,
3. the date and the operator,
4. unplanned events of significance from a radiation protection point of view,
5. the result of contamination check and information on decontamination.

### **Storage of radioactive substances**

§ 30 Radioactive substances shall be stored under lock in a way that prevents access by unauthorised persons. The storage shall be safe in case of fire.

The storage shall be shielded so that the dose-rate does not exceed 20 microsievert per hour ( $\mu\text{Sv/h}$ ) where persons temporarily might be, or 2  $\mu\text{Sv/h}$  where they permanently might be.

§ 31 The storage shall be easy to clean. If there are volatile substances, or a risk that such could be produced, the storage shall be well ventilated.

§ 32 The storage shall be marked with the warning symbol for ionising radiation<sup>6</sup>, the text "Förvaringsplats för radioaktiva ämnen"\* and information about the name and telephone number of somebody who is in charge of the storage.

<sup>6</sup> The warning symbol for ionising radiation is provided in Svensk Standard SIS 031210 "Bildsymboler för märkning". The symbol is identical to the symbol provided in Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work, OJ L 245, 26.8.29, p. 23, (Celex 392L0058).

\* "Radioactive substances are stored here"

§ 33 A storage container shall be made of a material that is suitable with respect to the physical and chemical properties of the substance that is stored. The container shall be marked with information about the nuclide and its activity at a specified date.

§ 34 The sections 30-33 shall also apply on radioactive waste pending the final handling.

#### **Transport**

§ 35 An instruction for transport of radioactive substances shall be available. The instruction shall concern planning, supervision, marking and the kind of container. Internal transports shall, as far as it is practically possible, be performed on the same safety level as external transports on roads<sup>7</sup>.

#### **Documentation**

§ 36 Information on the following items shall be recorded, signed and kept easily available to personnel concerned:

1. received and stored radioactive substances and their activities,
2. the possessed sources for calibration,
3. the results of checks on ventilation and contamination,
4. the results of personal dosimetry and the estimated internal doses.

§ 37 Unplanned events of significance from a radiation protection point of view shall as soon as possible, however not later than after one week, be reported to the Swedish Radiation Protection Institute.

#### **Exception**

§ 38 If there are particular reasons the Swedish Radiation Protection Institute may grant exception from these regulations.

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These regulations enter into force on October 1, 2000, when the Swedish Radiation Protection Institute's Regulations (SSI FS 1990:5) on Marking with Radioactive Iodine and the Swedish Radiation Protection Institute's regulations (1993:2) on Extensive Laboratory Work with Radioactive Substances shall cease to apply.

The regulations replace the corresponding rules earlier given as conditions for licences.

#### **Provisional regulations**

Concerning practices for which licences have been granted before October 1<sup>st</sup> 2000, it is sufficient if the sections 8 and 28 are met at the latest on July 1<sup>st</sup>, 2001.

On behalf of the board of the Swedish Radiation Protection Institute

LARS-ERIK HOLM

Birgitta Ekström

<sup>7</sup> For transport of radioactive substances, regulations by the Swedish Rescue Services Agency apply, given on the basis of the Law (1982:821) on Transport of Hazardous Goods. Regarding transport on roads ADR applies.

**Activity limits per each sub-operation defining extensive work for different radio toxicity Classes**

Kind of work *	Activity (MBq)		
	Class B	Class C	Class D
Work at risk of internal contamination by inhalation, i.e. handling of radioactive gas or powder and mechanical processing of solid radioactive substances	1	10	100
Work at risk of external and internal exposure, but with low risk of contamination by inhalation, i.e. handling of radioactive solutions at chemical analysis, synthesis, marking, preparation and animal experiments	10	100	1000
Work at low risk of exposure, i.e. simple handling of a small amount (for dilution) from a stock solution	100	1000	10000

\* The distribution of sub-operations is neither exact, nor rigid. It is based upon the risk of internal contamination, spread of radioactive substances etc.

**Classification of radio nuclides according to radio toxicity**

## Class A (very high toxicity)

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Pb-210	Po-208	Po-210	Ra-226	Ra-228
Ac-227	Th-227	Th-228	Th-230	Pa-231
U-230	U-232	U-233	U-234	Np-237
Pu-238	Pu-239	Pu-240	Pu-241	Pu-242
Am-241	Am-243	Cm-242	Cm-243	Cm-244
Cf-252				

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## Class B (high toxicity)

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Na-22	Cl-36	Ca-45	Sc-46	Mn-54
Co-56	Co-60	Ge-68	Sr-89	Sr-90 +
Y-91	Zr-95	Ru-106 +	Ag-110m	Cd-115m
In-114m	Sb-124	Sb-125	I-124	I-125
I-126	I-131	I-133	Cs-134	Cs-137 +
Ba-140 +	Ce-144 +	Eu-152 (13 y)	Eu-154	Tb-160
Tm-170	Ta-182	Ir-192	Tl-204	Pb-212 +
Bi-207	Bi-210	At-210	At-211	Ra-224 +
Ac-228	Th-234 +	Pa-230	U-236	

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## Class C (moderate toxicity)

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Be-7	C-14	F-18	Na-24	P-32
P-33	S-35	Cl-38	Ar-41	K-42
K-43	Ca-47	Sc-47	Sc-48	Cr-51
Mn-56	Fe-55	Fe-59	Co-57	Co-58
Ni-63	Ni-65	Cu-64	Zn-65	Zn-69m
Ga-67	Ga-72	As-74	As-76	Se-75
Br-82	Kr-85	Kr-87	Rb-81	Rb-86
Sr-85	Sr-91	Y-90	Zr-97 +	Nb-93m

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to be continued

## Class C (moderate toxicity, continuation)

Nb-95	Mo-99	Tc-96	Tc-97	Tc-97m
Tc-99	Ru-97	Ru-103	Ag-105	Ag-111
Cd-109	Cd-115	In-111	In-115m	Sn-113
Sn-125	Te-125m	Te-127	Te-129	Te-131m
Te-132	I-123	I-130	I-132	I-134
I-135	Xe-135	Cs-131	Ba-131	La-140
Ce-141	Ce-143	Pm-147	Eu-152 (9.2 h)	Gd-159
Er-169	Tm-171	Yb-175	Lu-177	W-181
W-185	W-187	Os-185	Au-198	Au-199
Hg-197	Hg-197m	Hg-203	Tl-201	Tl-202
Pb-203	Bi-206	Bi-212 +	Rn-220 +	Rn-222 +
Th-231	Pa-233			

## Class D (low toxicity)

H-3	C-11	N-13	O-15	Ar-37
Ni-59	Zn-69	Ga-68	Ge-71	Rb-87
Sr-85m	Sr-87m	Y-91m	Zr-93 +	Nb-97
Tc-96m	Tc-99m	In-113m	I-129	Xe-131m
Xe-133	Cs-134m	Cs-135	Th-232 sec	Th-Nat
U-235 +	U-238 +	U-Nat		

The notation "+" or "sec" after a nuclide indicates the mother nuclide and its daughters in equilibrium. The belonging to a certain Class is determined by the mother nuclide.

Information about the Class of nuclides that are not included in the tables can be provided by the Swedish Radiation Protection Institute.