Application Form – Part 1



Gener	al information al	bout the undertaking:	
Name	of undertaking:		
Organi	sation number:		
Visitin	g address:		Post code:
Town:			
Postal	address:		Post code:
Town:			
Tel.:		, Fax:, E-mail:	
Interne	et address:		
The ap	plication relates	to:	
□ New	authorisation (F	irst-Time Applicant).	
□ Cha	nge/addition to e	existing authorisation(s). Enter authorisation number:	
□ Ren	ewal of existing a	authorisation(s). Enter authorisation number:	
	case of a change of the form.	e, addition or renewal, this should be specified in a separate att	tachment, unless it is covered by part
-		ply, pursuant to the Regulations on Radiation Protection ans) Section 9, for authorisation for the following category/io	
a)	☐ Acquisition,	use and maintenance of industrial radiography equipment.	
b)	treatment, ster	and use of radiation sources for irradiation of animals, other bi rilisation, hardening or other purposes. This does not apply to nts in Section 24, paragraph 3.	
c)	•	and use of sealed radioactive sources for logging operations, con of structures around boreholes.	or accelerators for the
d)	□ Extensive, no	on-medical radiation use for research.	
e)	•	and administration of radiopharmaceuticals or substances in c gnostics and therapy.	connection with medical and
f)	☐ Acquisition a	and use of equipment for radiotherapy on humans.	
g)	radiography an	and use of X-ray diagnostic apparatus within the health sector nd fluoroscopy, angiography and intervention procedures, com v. The acquisition and use of simple X-ray diagnostic equipmen requirement.	puted tomography (CT) and
h)	☐ Acquisition a	and non-medical use of accelerators, except electron microsco	opes.
i)	□ Manufacture	e and import of radiopharmaceuticals.	
j)		radioactive substances to products, and/or sale of such produ Section 2, paragraph five is exempt from the authorisation requ	
k)	□ Manufacture	e of radioactive radiation sources.	
l)	☐ Acquisition a	and use of open radioactive sources for tracer examinations o	utside the laboratory.
m)	•	and use of sealed radioactive sources with activity levels great the appendix to this regulation.	er than 2 x 10 ⁶ times the exemption
n)	□ Acquisition a	and use of onen radioactive sources requiring type Δ isotone b	aboratory; of Section 27

0)	☐ Acquisition and use of ionising radiation to check persons a purpose.	nd use of radiological equipment for non-medical			
р)	 □ Import and export of high activity radioactive radiation sources. □ Extraction of radioactive substances in connection with mining operations. □ Sale and leasing of radiation sources. Authorisation requirements do not apply to radiation sources and areas of use mentioned in Section 2, paragraphs five and six. □ Acquisition and use of magnetic resonance imaging (MR) for medical purposes. 				
q)					
r)					
s)					
t)	$\hfill\square$ Import or manufacture of solariums for cosmetic purposes.				
Radiat	ion Protection Coordinator (cf. Section 17):				
	dertaking may have several radiation protection coordinators. Con protection coordinator.	One of them must be designated as the central			
Name	of (central) radiation protection coordinator:				
Postal	address:	Post code:			
City:		_			
Tel. (Di	rect):, E-mail:				
Applic	ation form Part 2 for relevant categories (a-t) is attached to	the application: □ Yes □ No			
Numbe	er of Part 2 application forms attached to the application:				
Applic	ation form Part 3 for relevant categories (a-t) is attached to	the application: □ Yes □ No			
Numbe	er of Part 3 application forms attached to the application:				
Attach	ments:				
Numbe	er of other attachments:				
Data					
-	ure:				
	al manager of the undertaking)				
In bloc	k letters:				

APPLICATION FOR APPROVAL - PART 2

CATEGORY R: SALE AND LEASING OF RADIATION SOURCES



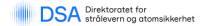
Part 2 must be completed in addition to Part 1 of the application form. The requested information/documentation should be attached to the application. Insert comments where applicable. Section references refer to the Radiation Protection Regulations, which can be found at lovdata.no (in Norwegian only).

The undertaking

An undertaking may have administrative responsibility for one or more associated entities, e.g. divisions in multiple locations in Norway.

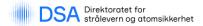
Attach:

 Organisation chart for the undertaking. If the undertaking has multiple entities, please state which of them are engaged in leasing/selling of radiation sources. The chart should also identify the radiation protection coordinator(
Append	dix no			
The undertaking has approval for selling and/or leasing of radiation sources from the authorities in other Nordic or European countries				
Comme	ents:			
The ເ	ındertaking's services			
Functio	ons provided			
	Sales of radiation sources			
	Rental/leasing of radiation sources			
	Installation of radiation sources			
	Maintenance and service of radiation sources/equipment.			
	Quality control of equipment			
	Guidance on shielding			
	Design of rooms for the use of radiation sources			
	Calibration of equipment and devices for dose measurement			
	Training in the use and handling of radiation sources			
	Return scheme for sources that have been taken permanently out of use			
	Other (please specify):			



Radiation sources to be sold/leased by the undertaking:

Radiotherapy	y:
	\square Linear accelerator for radiotherapy
	\square X-ray apparatus for radiotherapy
	□ > 50 kV
	☐ Grenz ray unit
	\square Radioactive sources for brachytherapy
	\square Equipment with radioactive sources for external radiation therapy (gamma knife etc)
	☐ CT for dose planning
	☐ MRI for dose planning
	☐ Other (please specify):
Medical diag	nostic equipment:
	☐ Dental X-ray equipment (excl. CBCT)
	☐ Dental X-ray equipment (incl. CBCT)
	☐ X-ray equipment for chiropractors
	☐ Bone density scanners
	☐ Mammography equipment
	\square X-ray equipment for angiographic and interventional procedures
	☐ Conventional X-ray equipment
	□ст
	□ MR
	□ PET/MRI
	□ PET/CT
	□ SPECT/CT
	☐ Other (please specify):
Open radioad	ctive sources:
	\square Radiopharmaceuticals or substances for use in medical and veterinary diagnostics or therapy
	\square Radiochemicals for use in laboratories for research, teaching or analysis purposes
	\square Radioactive tracers for use in tracer studies outside the laboratory



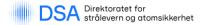
Sealed radioa	active sources:	
	\square Nuclear gauges in fixed installations (level gauges, multiphase meters, density gauges, etc.)	
	☐ Well logging sources	
	\square Mobile sources (portable moisture density gauges, liquid level gauges, etc.)	
	□ Irradiators	
	\square Source containers and/or sources for industrial radiography	
	\square Sources for calibration, stability testing, demonstration or education	
	\square Laboratory/measuring equipment with sealed radioactive sources	
	☐ Other:	
Equipment for technical/industrial or research use		
	\square X-ray equipment for technical/industrial use	
	\square X-ray equipment for veterinary use	
	☐ Accelerator	
	☐ Other (please specify):	

Overview of radiation sources to be sold or leased:

Attach:

- For X-ray equipment: Overview including type, manufacturer, and standards the products are approved according to.
- For open or sealed radioactive sources: Overview including application, manufacturer, radionuclides, activity levels and standards met by the source capsule.

Appendix no.



2.1. The undertaking's internal control regarding radiation protection

The Radiation protection legislation shall be implemented in the undertaking's internal control system. The quality system shall ensure internal control and comply with the requirements for documentation. This chapter deals with Section 5 of the Internal Control Regulations in addition to the sections of the Radiation Protection Regulations referred to.

Systems that ensure radiation protection (Section 17 of the Radiation Protection Regulations, Section 5 of the Internal Control Regulations)

The undertaking can have one or more radiation protection coordinators. For undertakings that do not handle the radiation sources themselves, a radiation protection coordinator must be appointed to act as a link to customers/lessees and to the DSA. If several radiation protection coordinators are appointed, a central coordinator must be designated to handle these tasks.

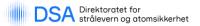
The undertaking must have a system to handle radiation protection to the extent required
Attach:
 Description of the tasks/responsibilities of the radiation protection coordinator (and any radiation protection contacts).
Appendix no:
Procedures in the quality system (Section 16)
The undertaking's procedures and instructions concerning radiation protection can be found in the quality system.
Not relevant (the undertaking does not handle/store radiation sources)
Risk assessment and physical security (Section 18)
The undertaking has carried out risk assessments concerning storage and handling of radiation sources
Stored radiation sources are properly secured
Not relevant (the undertaking does not handle/store radiation sources)
Duty to notify accidents and abnormal events (Section 20)
The undertaking has procedures for reporting accidents, incidents or abnormal events involving radiation
Not relevant (the leasing company does not handle/store radiation sources)
2.2. Radiation protection (HSE)
Personal dosimetry (Sections 31, 33, 34)
Applies to undertakings that store, install and/or do maintenance of radiation sources.
The undertaking shall classify exposed workers in category A or B (cf. Section 31). All exposed workers in category A and exposed workers in category B who could receive an effective dose above 1 mSv/year shall have their individual radiation exposure measured, for example by using a personal dosimeter.
An assessment has been made to determine who shall use a personal dosimeter
Comments:
Radiation shielding in buildings (Sections 6 and 25)
Applies to undertakings that store radioactive sources and/or use X-ray equipment installed on the undertakins's own premises.
All rooms where X-ray equipment is used are shielded to ensure that the requirements regarding

Rooms/cabinets for storing radioactive sources meet the requirements described in Section 25



Overview of sources (Sections 13, 14, 21) The undertaking has an updated register of all radiation sources and where they are located For open radioactive sources: The undertaking has updated lists of radionuclides and activity levels. For radioactive sources: The undertaking offers a return scheme for sources that have been taken permanently out of use The radiation sources are sent to: The Institute for Energy Technology (IFE) Foreign manufacturer/dealer Other: State here: Registering of radiation sources (Sections 11, 13) The undertaking registers radiation sources, subject to registration in the DSA's electronic registration system and informs its customers about their duty of registration 2.3. Competence The undetaking's competence and customer training (Sections 11, 16, 49): The Norwegian Radiation and Nuclear Safety Authority may attach conditions to the authorisation covering e.g. competence in radiation protection, depending on the services that the undertaking offers. For undertakings that offer device/equipment-specific user training: The undertaking has the competence to provide device-specific user training which includes radiation protection and proper and safe use of radiation sources that are sold/leased out For undertakings that carry out service and maintenance: The undertaking has competence to carry out service and maintenance of radiation sources that are sold/leased For undertakings that perform quality controls of radiation sources: The undertaking has competence to perform quality controls of radiation sources that are sold/leased 2.4. **Technical requirements** Requirements concerning radiation sources (Sections 22, 24) The radiation sources have been produced in accordance with the relevant ISO standards Ionising radiation sources are marked with the standard symbol for ionising radiation according to the Norwegian standard NS-1029 Applies to distributors of sealed radioactive sources. The source capsule is manufactured in accordance with ISO 2919 Applies to equipment for imaging and analysis in industrial and research use Industrial nuclear gauges in fixed installations meet the requirements of ISO 7205 for class xx2323xxxx with respect to radiation leakage. Applies to fixed equipment in closed systems for non-medical imaging and technical analyses (X-ray equipment in processes, laboratory equipment containing sealed radioactive sources or X-ray tubes, baggage X-ray and body imaging equipment, etc.)

The radiation sources are shielded so the surface dose rate does not exceed 5 µSv/h



X-ray machines: Radiation is generated only by using a code/key. with light or sound signals that indicate when radiation is being generated		
lies to X-ray equipment for technical/industrial use: Radiation is generated only using a code/key, I light or sound signals that indicate when radiation is being generated		
Measuring equipment for radiation protection (Sections 11 and 26)		
Applies to dealers who store radioactive sources.		
The undertaking has measuring equipment available to control radiation shielding and radioactive		
contamination		
Customer register (Section 11)		
The undertaking has a documentation system set up for annual reporting of sources sold and/or leased out (details of customers and technical specifications of the radiation sources)		
Vigilance reports (Section 11)		
Vigilance reports are reports from manufacturers on general faults or issues in radiation sources and any recalls of radiation sources.		
The undertaking has routines for making vigilance reports from its own equipment producers/manufacturers known to the affected customers		
Comments:		
Confirmation:		
I confirm that the documentation showing that the regulatory requirements are met and complied with, is held within the undertaking and is available to the Norwegian Radiation and Nuclear Safety Authority for inspection/supervisory purposes.		
Date:		
Signature:		
(for the undertaking)		
In block letters:		