Application Form – Part 1

DSA Norwegian Radiation and Nuclear Safety Authority

General information about the undertaking:

Name of undertaking: _____

Organisation number: _____

Visiting address: _____ Post code: _____

Town: _____

Postal address: _____ Post code: _____

Town: _____

Tel.: _____, Fax: _____, E-mail: _____

Internet address: _____

The application relates to:

☐ New authorisation (First-Time Applicant).

☐ Change/addition to existing authorisation(s). Enter authorisation number: _____

☐ Renewal of existing authorisation(s). Enter authorisation number: _____

In the case of a change, addition or renewal, this should be specified in a separate attachment, unless it is covered by part 2 or 3 of the form.

I, the undersigned, apply, pursuant to the Regulations on Radiation Protection and Use of Radiation (Radiation Protection Regulations) Section 9, for authorisation for the following category/ies:

a) ☐ Acquisition, use and maintenance of industrial radiography equipment.

b) ☐ Acquisition and use of radiation sources for irradiation of animals, other biota, materials, products etc. for treatment, sterilisation, hardening or other purposes. This does not apply to closed X-ray facilities complying with the requirements in Section 24, paragraph 3.

c) ☐ Acquisition and use of sealed radioactive sources for logging operations, or accelerators for the characterisation of structures around boreholes.

d) ☐ Extensive, non-medical radiation use for research.

e) ☐ Acquisition and administration of radiopharmaceuticals or substances in connection with medical and veterinary diagnostics and therapy.

f) ☐ Acquisition and use of equipment for radiotherapy on humans.

g) ☐ Acquisition and use of X-ray diagnostic apparatus within the health sector, including ordinary X-ray radiography and fluoroscopy, angiography and intervention procedures, computed tomography (CT) and mammography. The acquisition and use of simple X-ray diagnostic equipment giving low doses is exempt from the authorisation requirement.

h) ☐ Acquisition and non-medical use of accelerators, except electron microscopes.

i) ☐ Manufacture and import of radiopharmaceuticals.

j) ☐ Addition of radioactive substances to products, and/or sale of such products. The sale of consumer products mentioned in Section 2, paragraph five is exempt from the authorisation requirement.

k) ☐ Manufacture of radioactive radiation sources.

l) ☐ Acquisition and use of open radioactive sources for tracer examinations outside the laboratory.

m) ☐ Acquisition and use of sealed radioactive sources with activity levels greater than 2×10^6 times the exemption limits stated in the appendix to this regulation.

n) ☐ Acquisition and use of open radioactive sources requiring type A isotope laboratory; cf. Section 27.

o) ☐ Acquisition and use of ionising radiation to check persons and use of radiological equipment for non-medical purpose.

p) ☐ Import and export of high activity radioactive radiation sources.

q) ☐ Extraction of radioactive substances in connection with mining operations.

r) ☐ 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.

s) ☐ Acquisition and use of magnetic resonance imaging (MR) for medical purposes.

t) ☐ Import or manufacture of solariums for cosmetic purposes.

Radiation Protection Coordinator (cf. Section 17):

The undertaking may have several radiation protection coordinators. One of them must be designated as the central radiation protection coordinator.

Name of (central) radiation protection coordinator: _____

Postal address: _____ Post code:_____

City: _____

Tel. (Direct): _____, E-mail: _____

Short description of competence (education, experience, training, etc.): _____

_____

_____

Application form Part 2 for relevant categories (a-t) is attached to the application: ☐ Yes ☐ No

Number of Part 2 application forms attached to the application:

Application form Part 3 for relevant categories (a-t) is attached to the application: ☐ Yes ☐ No

Number of Part 3 application forms attached to the application:

Attachments:

Number of other attachments:

Date: _____

Signature: _____

(General manager of the undertaking)

In block letters:

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(s).

Appendix no. _____

The undertaking has approval for selling and/or leasing of radiation sources from the authorities in other Nordic or European countries

Comments: _____

_____

_____

The undertaking's services

Functions 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:

- ☐ Linear accelerator for radiotherapy
- ☐ X-ray apparatus for radiotherapy
  - ☐ > 50 kV
  - ☐ Grenz ray unit
- ☐ Radioactive sources for brachytherapy
- ☐ Equipment with radioactive sources for external radiation therapy (gamma knife etc)
- ☐ CT for dose planning
- ☐ MRI for dose planning
- ☐ Other (please specify): _____

Medical diagnostic equipment:

- ☐ Dental X-ray equipment (excl. CBCT)
- ☐ Dental X-ray equipment (incl. CBCT)
- ☐ X-ray equipment for chiropractors
- ☐ Bone density scanners
- ☐ Mammography equipment
- ☐ X-ray equipment for angiographic and interventional procedures
- ☐ Conventional X-ray equipment
- ☐ CT
- ☐ MR
- ☐ PET/MRI
- ☐ PET/CT
- ☐ SPECT/CT
- ☐ Other (please specify): _____

Open radioactive sources:

- ☐ Radiopharmaceuticals or substances for use in medical and veterinary diagnostics or therapy
- ☐ Radiochemicals for use in laboratories for research, teaching or analysis purposes
- ☐ Radioactive tracers for use in tracer studies outside the laboratory

Sealed radioactive sources:

- ☐ Nuclear gauges in fixed installations (level gauges, multiphase meters, density gauges, etc.)
- ☐ Well logging sources
- ☐ Mobile sources (portable moisture density gauges, liquid level gauges, etc.)
- ☐ Irradiators
- ☐ Source containers and/or sources for industrial radiography
- ☐ Sources for calibration, stability testing, demonstration or education
- ☐ Laboratory/measuring equipment with sealed radioactive sources
- ☐ Other: _____

Equipment for technical/industrial or research use

- ☐ X-ray equipment for technical/industrial use
- ☐ 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 dose limits are fulfilled ..... ☐

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 ..... ☐

Applies to X-ray equipment for technical/industrial use: Radiation is generated only using a code/key, with 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: _____