Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate
Radiation Protection Division

Licence ID (leave blank)

Application form
Trade, installation and quality tests by specialist companies (diagnostic and therapy systems and/or image detector systems, image monitor systems, gamma cameras, activimeters and non-medical installations)

The following additional documents must be enclosed:

- Documents to be submitted according to the activity to be licensed under Point 3
- Training certificate(s) of radiological protection expert(s) or confirmation of registration

Application and enclosures must be submitted to:

- str@bag.admin.ch (send enclosures as separate PDF files) *or*
- Federal Office of Public Health, Radiation Protection Division, CH-3003 Bern

1 Applicant details

1.1 Legal entity or individual

Name (individual) or company (legal entity)

Unique Business Identification Number (UID)

Legal domicile (applicant's business address/place of residence)

Street and number

Post office box

Postcode and city

Canton / Country

Contact person

Gender

☐ m ☐ f

Title

Last name

First name

Email address

Phone/mobile number

1.2 Division (if applicable)

Name/name of division

Site address of division ☐ Same address as legal domicile (1.1)

Street and number

Post office box

Postcode and city

Canton / Country

Contact person, division ☐ Same person as under 1.1

Gender

☐ m ☐ f

Title

Last name

First name

Email address

Phone/mobile number

1.3 Correspondence address

Email address for electronic delivery

Correspondence address in Switzerland (for delivery by mail)

→ A correspondence address in Switzerland is mandatory and must be indicated in all cases.

☐ Same as legal domicile under 1.1 (only possible if in Switzerland)
☐ Same as site address of division under 1.2 (only possible if in Switzerland)

→ Always fill in, if different from 1.1 or 1.2, or if the legal domicile is outside of Switzerland.

Name (individual) or company (legal entity)

Reference/supplement

Street and number

Post office box

Postcode and city

Canton

1.4 Invoice address

☐ Same as legal domicile
☐ Same as division site address
☐ Same as correspondence address

If different from legal domicile, site address or correspondence address

Name or company

Reference/supplement

Street and number

Post office box

Postcode and city

Canton / Country

2 Information on the application

2.1 Reason for application

☐ New application

☐ Change / adjustment of an existing licence →

Existing licence ID

Description of change / adjustment

3 Activity to be licensed

3.1 Information on the activity and documents to be submitted

For what type of installation generating ionising radiation would you like to apply for a licence to conduct trade / installation / quality tests?

☐ Medical installations (diagnostic or therapy systems for humans or animals)

☐ Non-medical installations (no medical use on humans or animals)

Activity		Documents to be submitted
☐ Trade only (purchase and sale) and/or rental of installations or systems	→	▪ Description of company and its goals ▪ Organisational structure, responsibilities ▪ Process organisation, description of processes ▪ Product overview ('product list') ▪ Contractual agreement with a licensed specialist company for the installation and quality assurance of equipment (*for medical installations only*) *→ The FOPH may demand additional documents if required.*

Activity(ies)		Documents to be submitted
- Trade (purchase and sale) of installations or systems - Installation and quality assurance tests *For medical installations also if applicable:* - operation - Radiation protection follow-up inspection - Quality assurance measures on installations, imaging systems and activimeters in nuclear medicine, or image detector and monitor systems used in medical diagnostics **System(s) concerned by the activity:** ☐ For installation and quality assurance tests on systems in the **low or medium dose range** (effective dose for patients < 5 mSv; dental, peripheral skeleton, x-ray imaging of the chest and trunk) ☐ For installation and quality assurance tests on systems in the **high dose range**, including **therapy systems and accelerators** (effective dose for patients > 5 mSv: interventional radiology, CT, nuclear medicine, x-ray therapy systems, radiotherapy, teletherapy) ☐ For installation, maintenance and checking of non-medical equipment (no medical use on humans or animals)	→	▪ Description of the company and its goals ▪ Organisational structure, responsibilities ▪ Process organisation, description of processes (e.g. scope and frequency of testing according to legal requirements) ▪ Product overview (product list) * ▪ Qualifications of staff (training list) * ▪ Measuring equipment (list of measuring devices used with current verification data) ▪ Declaration of conformity for medical products (*medical installations only*) ▪ Templates of protocols for the acceptance/status and constancy test (constancy test *for medical installations only*), which take into account the required scope of the tests. * The product and training lists may be omitted if the requirements for *process-based* quality management according to ISO 13485 are met (cf. paragraph II of the directive R-06-01 of the FOPH). *→ The technical quality assurance protocols must be written in the company's standard language. The FOPH may request additional documents if necessary.*

Activity		Documents to be submitted
☐ Exclusively quality assurance tests on image detector systems or image monitor systems used in medical diagnostics	→	▪ Description of the company and its goals ▪ Organisational structure, responsibilities ▪ Submission of protocols for the acceptance/status and constancy test, which take into account the required scope of the tests ▪ Measuring equipment (list of measuring devices used with current verification data) If quality assurance measures are performed on *image detector systems*, also: ▪ Process organisation, description of processes (e.g. scope and frequency of quality assurance tests according to legal requirements) ▪ Product overview ('product list') *→ The technical quality assurance protocols must be written in the company's standard language. The FOPH may request additional documents if necessary.*

Activity		Documents to be submitted
☐ Exclusively quality assurance tests on installations, imaging systems and measuring devices (activimeters) in nuclear medicine	→	▪ Description of the company and its goals ▪ Organisational structure, responsibilities ▪ Process organisation, description of processes (e.g. scope and frequency of quality assurance tests according to legal requirements) ▪ Product overview ('product list') * ▪ Qualifications of staff ('training list') * ▪ Measuring equipment (list of measuring devices used with current verification data) ▪ Declaration of conformity for medical products ▪ Templates of protocols for the acceptance/status and constancy test, which take into account the required scope of the tests * *The product and training lists may be omitted if the requirements for process-based quality management according to ISO 13485 are met (cf. Annex 2 to the directive L-08-04 of the FOPH).* *→ The technical quality assurance protocols must be written in the company's standard language. The FOPH may request additional documents if necessary.*

Operation of an in-house x-ray system on the company premises

Is the operation of one or more in-house x-ray systems planned within the company premises?

☐ Yes
☐ No

If yes, state the purpose

☐ Test operation
☐ Demonstration
☐ Training
☐ Research

→ A separate application form must be submitted for the operation of a medical x-ray system or for the use of non-medical x-ray system.

4 Radiological protection expert(s)

4.1 Technical expertise

Gender	Title	Date of birth
☐ m ☐ f		

Last name	First name

Previous name (maiden name)	Occupation

Email address	Nationality

Training in Switzerland (completed or registered)

Date of completed training	/	Date of planned training as per binding registration

If training has been completed → Enclose training certificate	If training has not been completed → Enclose confirmation of registration

Recognition of foreign qualification

Date of recognition by the competent authorities	→	
Recognition outstanding: Application for recognition of a radiation protection qualification obtained abroad	→	☐ I confirm that the foreign qualification on radiation protection has been submitted to the competent authorities for recognition.

Training and continuing education

Radiological protection training requirement of expert	→	☐ I confirm that the obligation for continuing education according to the Radiological Protection Ordinance (scope and periodicity) is fulfilled.

Additional radiological protection experts

→ Report additional persons with the details under 4.1 by means of a separate enclosure

5 Conclusion of application

5.1 Other information and confirmations

Language of licensing decree

Desired language of licensing decree	→	☐ German ☐ French ☐ Italian

Confirmations by the applicant

Certificate of liability insurance	→	☐ I confirm that potential damage caused by ionising radiation is included in the liability insurance of the company.
Monitoring of occupational radiation exposure (dosimetry)	→	☐ I confirm that the radiation dose of all occupationally exposed persons in the company is monitored and that the requirements of the Dosimetry Ordinance are complied with.
Use of ionising radiation	→	☐ I confirm that the handling of ionizing radiation applied for will only take place once license has been issued by the FOPH.

Remarks

The applicant confirms that all information provided is true and consent for an electronic delivery of the licence.

Place	Date
Last name	First name
Function	