



Fact sheet

Mandatory licensing for the deployment of staff in supervised areas of medical establishments

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This fact sheet is aimed at medical device companies and medical technology companies that deploy staff in hospitals who are present during interventions with fluoroscopy in supervised areas. Deployed staff may be exposed to elevated levels of ionising radiation during these deployments. This fact sheet explains the legal foundations and sets out the criteria for cases in which staff are occupationally exposed. If staff are occupationally exposed, the medical device or medical technology company requires a licence from the Federal Office of Public Health.

Who is deemed to be occupationally exposed and must wear a dosimeter?

- Persons who are deployed for interventions with fluoroscopy in hospital at least once a week.

(Deployment of staff in controlled and supervised areas.)

or

- Persons who are deployed for fluoroscopy-guided interventional procedures in cardiology, angiology, urology and gastroenterology.

(Persons who through these deployments may exceed the effective dose of 1 mSv per calendar year, or the equivalent dose of 15 mSv for the lens of the eye or 50 mSv for the skin).

Radiological Protection Ordinance (RPO, SR 814.501), Articles 22, 51

When is a licence needed?

- Under Article 28 of the Radiological Protection Act (RPA; SR 814.50), a licence is required for anyone who handles radioactive substances or equipment and articles containing radioactive substances (let. a); anyone who manufactures, distributes, installs or uses installations and equipment capable of emitting ionising radiation (let. b); and anyone who administers ionising radiation and radioactive substances to humans (let. c).
- In addition to the activities specified in Article 28 of the RPA, or by way of clarification thereof, the following is also subject to mandatory licensing: the deployment of occupationally exposed persons as defined in Article 51 paragraphs 1 and 2 at one's own or at another establishment in Switzerland or abroad (Radiological Protection Ordinance RPO Art. 9, letter f).

- The deployment of persons in hospitals is therefore subject to mandatory licensing if these persons are present during interventions with fluoroscopy and are deemed to be occupationally exposed according to the criteria set out above.

Radiological Protection Act (RPA; SR 814.50), Article 28
Radiological Protection Ordinance (RPO, SR 814.501), Articles 9, 51

How can I apply for a licence?

- Submit your license application in the “Radiation Portal Switzerland”:
<https://www.gate.bag.admin.ch/RPS/ui/public-home>
- Select the license type ‘**Personalvermittlung in Kontroll-/Überwachungsbereichen**’ (‘Staff deployment in controlled/supervised areas’)
- You will find further information on licences in the area of radiation protection on our website:
[Radiation protection: licences, requirements and surveillance \(in German, French and Italian only\)](#)

What obligations does the licence entail?

- A radiological protection expert must be designated in the application. If nobody in the applicant company has the relevant basic or further training, the designated person must complete a 1-day course at Suva (deployment of staff in third-party companies – SPD (I 12)).
 If a person has completed a radiological protection course abroad, they can get this recognised in Switzerland. You will find further information and the link to the recognition form here:
[Recognition of radiological protection training undergone abroad](#)
- The accumulated radiation dose for deployed staff must be monitored on a monthly basis. Dosimeters should be procured from a recognised Swiss personal dosimetry service for this purpose.
[Personal dosimetry services](#)
- An internal directive on radiation protection should be submitted with the licence application. As a minimum requirement, it should describe the proper use of personal dosimetry and the how the deployed staff have been briefed.
- Duty to provide information: the licence holder must ensure that all deployed persons are appropriately informed about the health risks which may arise from handling ionising radiation.

Radiological Protection Ordinance (RPO, SR 814.501), Articles 19, 20, 21

Further information: Federal Office of Public Health, Health Protection Directorate, Radiation Protection Division, Tel. +41 58 462 96 14, str@bag.admin.ch, www.bag.admin.ch