

# Radiation Protection in Surgery

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## Legal Aspects of Radiation Protection in the Operating Theatre



# Disclosure

No conflicts of interest to disclose.

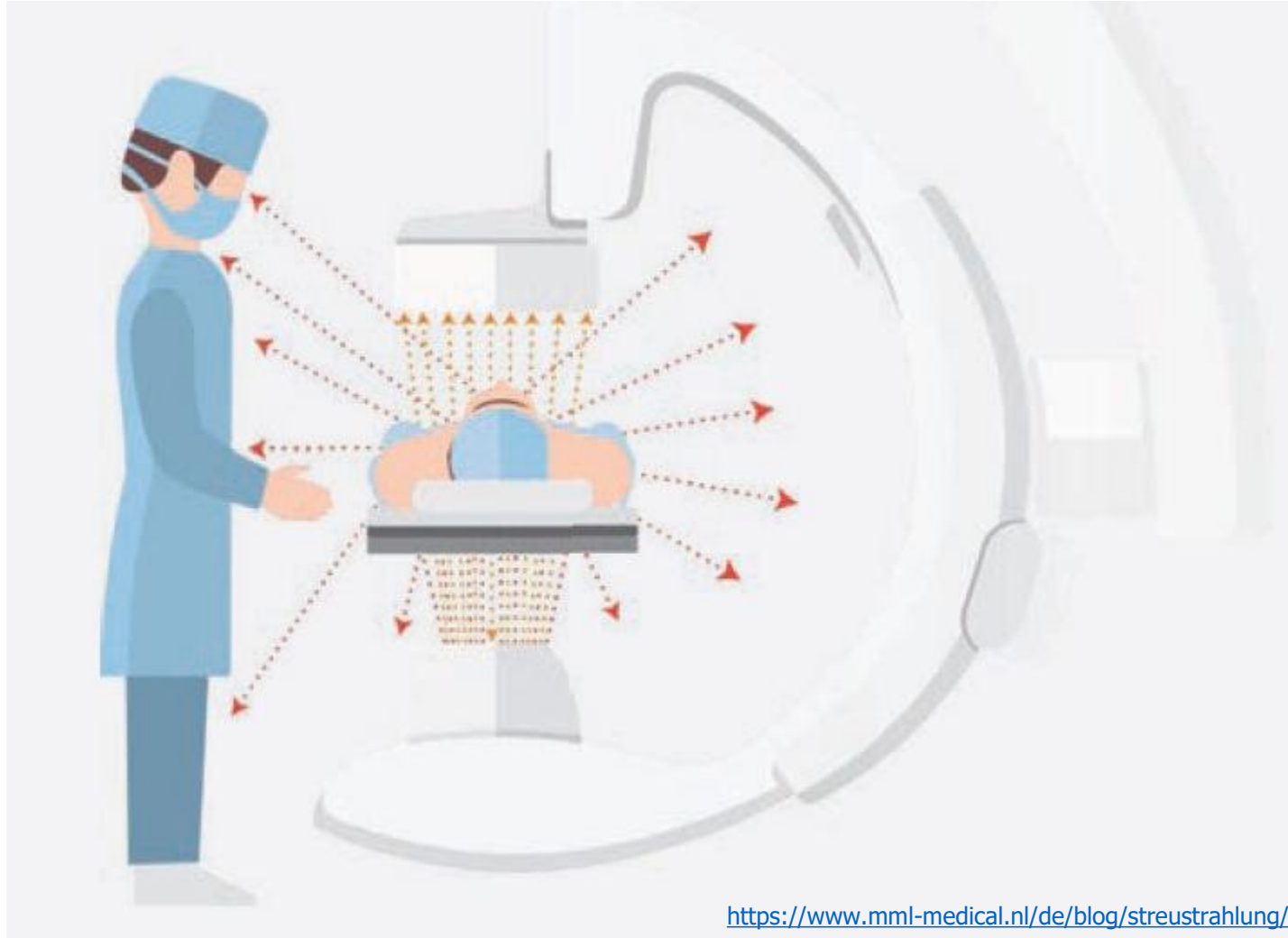


# Why is X-ray a problem at all?

## Radiation injuries

- Lens opacity (cataract)
- Skin damage
- Increase of cancer incidence

<https://www.iaea.org/resources/rpop/health-professionals/interventional-procedures>



<https://www.mml-medical.nl/de/blog/streustrahlung/>



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- 
- **Safe use of ionizing radiation**
  - **Protection of patients and staff against unnecessary radiation**

<https://www.mml-medical.nl/de/blog/streustrahlung/>





# Which legal requirements must be fulfilled for using an X-ray system in the operating theatre?

Use of protective equipment (lead aprons)

Wearing personal dosimeter

Setting up of supervised areas



Qualified and trained staff; instruction and continuous education

Compliance of the X-ray system

Optimized use of ionizing radiation



# When you use an X-ray system, you need a license!

A license is required by anyone who administers ionizing radiation and radioactive substances to humans (Radiological Protection Act, art. 28, lit. c).

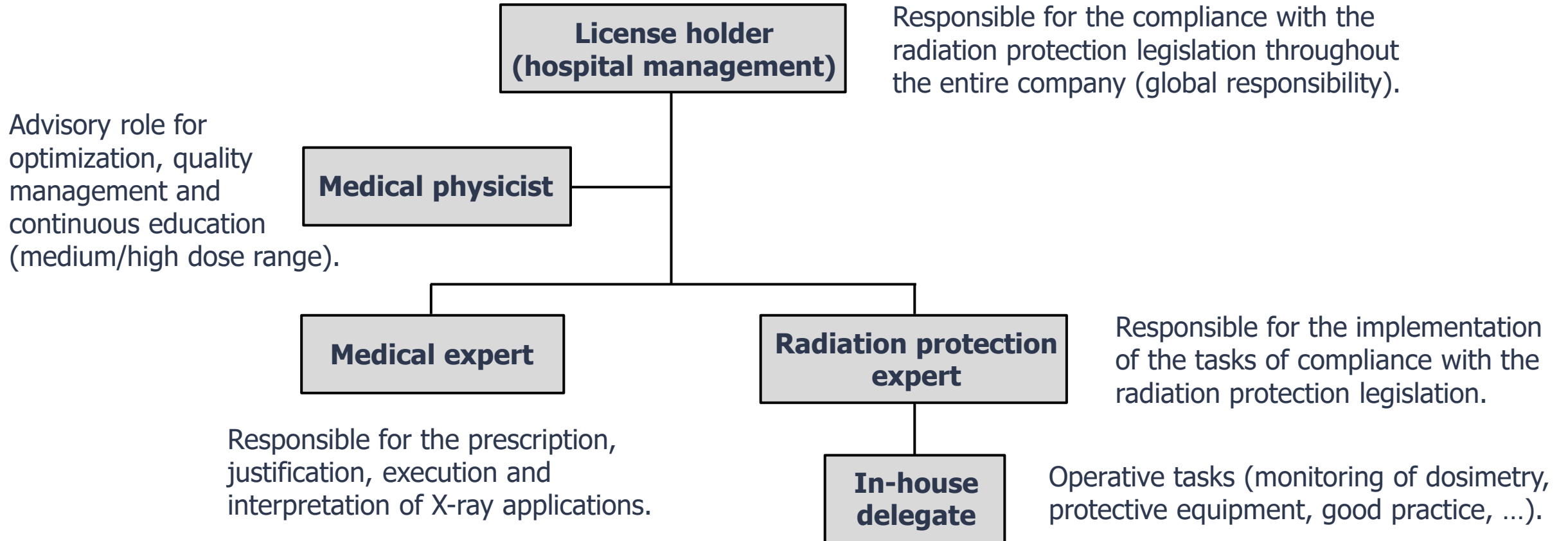
- Submission of application form to Federal Office of Public Health.

Requirements for approval:

- Responsibilities (license holder, medical expert, radiation protection expert);
  - X-ray system (specification, intended use, location);
  - Room shielding (plan, shielding calculation).
- 
- Installation / operation of an X-ray system only after a license has been issued by the FOPH.



# Radiation protection organization / responsibilities







# Radiation protection organization / responsibilities

**License holder  
(hospital management)**

Responsible for the compliance with the radiation protection legislation throughout the entire company (global responsibility).

Advisory role for  
optimization  
management  
continuous  
(medium/h

- Tasks can be delegated, but not the responsibility.
- Responsibilities in RP  $\neq$  Hierarchy in a hospital.
- Contact your ME, RPE, MP in radiation protection issues.

entation  
with the  
on.

Responsible for the prescription,  
justification, execution and  
interpretation of X-ray applications.

**In-house  
delegate**

Operative tasks (monitoring of dosimetry,  
protective equipment, good practice, ...).



# Setting up of supervised areas

Supervised areas must be established to limit and monitor radiation exposure (Radiological Protection Ordinance, art. 78 et seq.).

- Room shielding to protect persons in neighboring rooms.

Supervised areas must be marked with the hazard warning symbol.

- Operating theatres, rooms for preparation and post-treatment;
- Attention when entering supervised areas (sliding doors)!



Mini C-arms are also X-ray systems and must be used in supervised areas.

<https://www.ziehm.com/de/produkte/orthoscan-tau-1512/>

- The «2 m safety distance rule» is nonsense → lead apron and dosimeter must be worn!



# Setting up of supervised areas

Supervised areas must be established to limit and monitor radiation exposure (Radiological Protection Ordinance, art. 78 et seq.).

- Room shielding to protect persons in neighboring rooms.

Supervised areas must be marked with the hazard warning symbol.



- **Using an X-ray system outside supervised areas is not allowed.**

- Attention when entering supervised areas (sliding doors)!



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<https://www.ziehm.com/de/products/orthoscan-tau-1512/>

- The «2 m safety distance rule» is nonsense → lead apron and dosimeter must be worn!



# X-ray system

X-ray systems are medical devices (must have CE mark).

Installation and QA/maintenance is only allowed by authorized X-ray companies.

- Attention when purchasing X-ray systems abroad;
- Authorized X-ray companies are listed on FOPH website;

<https://www.bag.admin.ch/de/firmen-mit-bewilligung-fuer-handel-verleih-einrichtung-qs-von-roentgenanlagen>



# X-ray system

The medical exposure to ionizing radiation must be optimized (X-ray Ordinance, art. 4).

- Minimal dose to obtain necessary diagnostic information (ALARA principle);
- Different X-ray systems (performance, 2D/3D) of different vendors;
- Optimization tools (protocols, pulsation, use of apertures, ...).
- Instruction for qualified users by application specialists.
- Support during going live in clinical routine.
- Coaching / continuous education by MP and RPE.





# Dosimetry of occupationally exposed persons

Occupationally exposed persons means persons who:  
(Radiological Protection Ordinance, art. 51)

- In the course of their occupational activities or training may incur exposure which exceeds a dose limit of 1 mSv/year (members of the public);
- Work or undergo training at least once a week in supervised areas and may thus be exposed to an increased ambient dose rate.

Occupationally exposed persons must wear a dosimeter

- Carried under the lead apron on upper body or belly (pregnant);
- Sensitivity around 0.05-0.1 mSv → doses < 0.05 mSv are set to 0.







# Dosimetry of occupationally exposed persons

Duties of the license holder:

- Organization of personal dosimetry (duty of care);
- Regular communication of doses to staff;
- Reporting to FOPH in case of increases doses ( $> 2$  mSv/month, whole body or eye lens).

Special regulations for the dosimetry of affiliated physicians.

- They must wear a separate dosimeter at each hospital → doses must be assigned to each location (important in case of increased doses!).
- They must inform the other hospitals about their monthly accumulated doses (important for optimization purposes).

<https://www.bag.admin.ch/de/dosimetrie-und-berufliche-strahlenexposition>



# Dose limits for occupationally exposed persons

(Radiological Protection Ordinance, Art. 56-57)

**Whole body**



20 mSv/year

**Eye lens**



20 mSv/year

**Extremities**



500 mSv/year

**Under 16 years**



**16-18 years**



6 mSv/year

**Unborn child**



< 1 mSv during pregnancy



# Dosimetry for high-dose applications

For high-dose interventional examinations (e. g. vascular surgery, spine surgery), persons close to the patient must wear a second dosimeter over the lead apron.

- Estimation of doses of unprotected body parts (e. g. eye lens);
- Evaluation phase lasting at least 3 months to identify affected persons;
- Labelling of under-apron and over-apron dosimeter;
- Eye lens dosimeter integrated in lead glasses. (e. g. dosiEYE, dosilab).



<https://ssrpm.ch/wp-content/uploads/2021/12/recommendations-no17-eye-lens-dosimetry-2021-12.pdf>



Monitoring only works if dosimeters are worn all the time!





# Use of protective equipment for the staff

Occupationally exposed persons being present in supervised areas while an X-ray system is operated, must be protected by **suitable means**, in certain cases by **mobile or fixed protective equipment** (X-ray Ordinance, art. 24, al. 1).



<https://xprotec-swiss.ch/de/kategorie/strahlenschutz/koerperschutz/>



# Use of protective equipment for the staff

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The license holder must provide adequate protective equipment in sufficient quantity (X-ray Ordinance, art. 24, paragraph 2).

- «Adequate» → respecting body size.
- «Sufficient quantity» → depending on number of X-ray systems (and on the staff required for an intervention) that could be simultaneously used in the operating theatres.

<https://xprotec-swiss.ch/de/kategorie/strahlenschutz/koerperschutz/>



# Minimal protective equipment for the staff



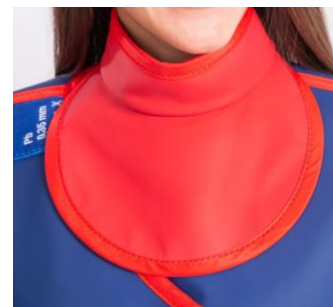
**Coat apron (front)**

Thickness  $\geq 0.25$  mm Pb  
At least 10 cm below knees



**Vest and skirt (all around)**

Thickness  $\geq 0.25$  mm Pb  
At least 10 cm below knees



**Thyroid protection**

Thickness  $\geq 0.5$  mm Pb



**Lead glasses**

Thickness  $\geq 0.5$  mm Pb

<https://xprotec-swiss.ch/de/kategorie/strahlenschutz/koerperschutz/>





# Minimal protective equipment for the staff



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**Thyroid protection**



**Lead glasses**

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It's not just about protecting the gonads!

<https://xprotec-swiss.ch/de/kategorie/strahlenschutz/koerperschutz/>



# Storage of protective equipment

The protective equipment must be stored (e. g. using coat hangers) and cleaned (hygiene issues) properly according to the instruction of the supplier (X-ray Ordinance, art. 24, al. 4).



Image in courtesy of Cantonal Hospital Aarau.



# Quality assurance of protective equipment

The protective equipment must be checked for proper functionality at least once a year (X-ray Ordinance, art. 24, al. 4).

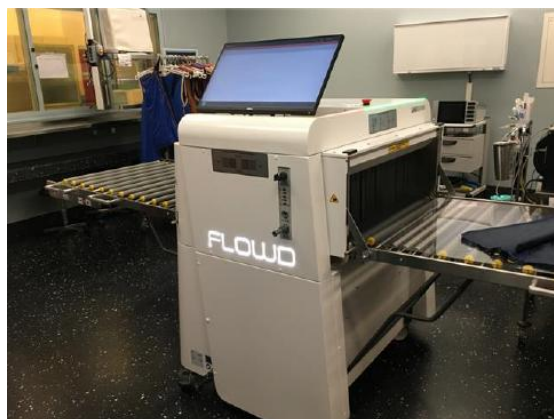
- Initial check for new purchased protective equipment recommended.

## Example of good practice: Protective equipment testing at Cantonal Hospital Aarau

Inventory of all equipment by QR codes and stickers



Screening of equipment using «baggage X-ray scanner» (FlowD, Linev Systems)



Classification of damages: insignificant, tolerable, severe  
Quantification of real lead thickness





# Continuous education

All occupationally exposed persons must follow a continuous education in radiation protection (Radiological Protection Ordinance, art. 172).

For staff in the operating theatre at least 8 lessons every 5 years (no recognition by FOPH required).

Hands-on training at own X-ray systems in own operating theatres by RPE, MP or vendor / supplemented by theoretical training (e-learning, lectures, conferences, ...).



# FOPH directive (d, f, i)

Working with ionizing radiation in surgical and interventional areas

<http://www.bag.admin.ch/str-wegleitungen>



Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione Svizzera  
Confederaziun svizra

Eidgenössisches Departement des Innern EDI  
Bundesamt für Gesundheit BAG  
Abteilung Strahlenschutz



**Wegleitung**  
Strahlenschutz im  
OP-Bereich  
V2 01.09.2024  
[www.bag.admin.ch/str-wegleitungen](http://www.bag.admin.ch/str-wegleitungen)

**Kontakt**  
Tel.: 058 452 95 14  
E-Mail: [str@bag.admin.ch](mailto:str@bag.admin.ch)

**Arbeiten mit ionisierender Strahlung im chirurgischen und interventionellen Bereich**

**Einleitung**

Diese Wegleitung richtet sich an das Personal, welches im Operationssaal, im Herzkatheter-Labor oder anderen interventionellen Bereichen der Medizin mit Röntgenstrahlung tätig ist. Sie bildet die gesetzlichen Vorgaben ab und hält sich an aktuelle Qualitätsstandards. Die Wegleitung beinhaltet modalitäts- und themenspezifische Informationen, die dem Personal der genannten Fachbereiche Unterstützung beim Arbeiten mit ionisierender Strahlung bieten.

**Bewilligungspflicht**

Jedes Röntgengerät benötigt eine Betriebsbewilligung des BAG, die vor der Inbetriebnahme erteilt worden sein muss. Zu diesem Zweck stellt die technisch sachverständige Person der Abteilung ein Bewilligungsgesuch an die Behörde. Die jeweilige Installationsfirma wirkt in diesem Prozess unterstützend mit. Voraussetzungen für die Erteilung einer Bewilligung sind, neben dem vollständigen Gesuchformular, den Qualifikationsnachweisen über die ausreichende fachliche und technische Kompetenz der sachverständigen Personen, sowie aktuelle Strahlenschutzpläne aller Räume (Überwachungsbereich), in denen die Anlage zum Einsatz kommen soll.

**Wichtig zu beachten:**  
Röntgengeräte dürfen erst nach Erteilung der Bewilligung installiert und genutzt werden. Die Verantwortlichkeiten und entsprechenden Aufgaben sind in der Strahlenschutzverordnung geregelt.

**Welche Aufgaben haben Bewilligungsinhaber:innen und Bewilligungsinhaber?**  
Bewilligungsinhaber:innen und Bewilligungsinhaber sind für die Einhaltung der Strahlenschutzvorschriften in ihrem Betrieb verantwortlich. Zu diesem Zweck setzen sie eine angemessene Anzahl von Strahlenschutz-Sachverständigen nach Artikel 16 des Strahlenschutzgesetzes ein und stellen diese Personen mit den erforderlichen Kompetenzen und Mitteln aus.

# Educational films (d, f, i)

General surgery, hand & foot surgery, hybrid OP, cardiology, angiology, urology

<http://www.bag.admin.ch/str-schulungsfilme>

← Strahlenschutz: Bewilligungen, Voraussetzungen und Aufsicht

**Informationen für medizinische Betriebe**

Diagnostische Referenzwerte im Strahlenschutz

Klinische Audits im Strahlenschutz

Rechtfertigungspraxis für ärztliche Zuweisenden und Zuweiser

Qualitätssicherung im Strahlenschutz

**Schulungsfilme zum Strahlenschutz für medizinische Betriebe**

**Schulungsfilme zum Strahlenschutz für medizinische Betriebe**

Die Abteilung Strahlenschutz des BAG hat eine Reihe von Schulungsfilmen für verschiedene Berufsgruppen in der Medizin produziert.

- ▼ Strahlenschutz in operativen und interventionellen Fachbereichen
- ▼ Strahlenschutz in der Nuklearmedizin
- ▼ Schulungsfilme für die Arbeit in der Radiopharmazie

**Strahlenschutz in operativen und interventionellen Fachbereichen**

Die folgenden Schulungsfilme informieren über praktische Strahlenschutzmassnahmen bei Durchleuchtungen in operativen und interventionellen Fachbereichen. Der erste Film deckt alle Fachbereiche ab (Langversion):

- Strahlenschutz in operativen und interventionellen Fachbereichen

Die vier nachfolgenden Filme sind Kurzversionen, die sich auf die für den jeweiligen Fachbereich relevanten Informationen konzentrieren:

- Strahlenschutz in der Hand- und Fusschirurgie
- Strahlenschutz in der Allgemein- und Spezialchirurgie
- Strahlenschutz in der Kardiologie, Angiologie und im Hybrid-OP
- Strahlenschutz in der Urologie

**Strahlenschutz in operativen und interventionellen Fachbereichen (Langversion)**



Strahlenschutz in operativen und interventionellen Fachbereichen (Langversion)

Ansehen auf YouTube





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Eidgenössisches Departement des Innern EDI  
**Bundesamt für Gesundheit BAG**

# Thank you for your attention!

