

99006018006000

# Operation of an X-ray facility or significant change in operation License

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/S1000020010000012053/S100002>

Modul	Sachverhalt
Leistungsschlüssel	99006018006000
Leistungsbezeichnung I	Operation of an X-ray facility or significant change in operation License
Leistungsbezeichnung II	Apply for the operation of an X-ray calibration facility or a significant change in the operation of an existing X-ray facility
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	<div lang="en-x-mtfrom-de">Registering an X-ray machine without a CE mark</div>, <div lang="en-x-mtfrom-de">Approval for X-ray</div>, <div lang="en-x-mtfrom-de">Report change to X-ray machine</div>

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Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	15.08.2022
Fachlich freigegeben durch	
Handlungsgrundlage	[§ 12 paragraph 1 number 4 and paragraph 2 StrlSchG](https://www.gesetze-im-internet.de/strlschg/_12.html)
Teaser	If you want to operate an X-ray device without type approval and without CE marking, you will need a permit.
Volltext	To operate an X-ray facility, you need approval from the responsible authority. If you want to make significant changes to the facility, you will also need permission. If you operate an X-ray device that has a type approval and/or CE mark, you do not need a permit.
Erforderliche Unterlagen	Submit the following documents with the signed written application from the person responsible for radiation protection: <ul style="list-style-type: none"> <li>• Plans, drawings and descriptions required to verify the approval requirements</li> <li>• Information that makes it possible to check whether <ul style="list-style-type: none"> <li>• the number of radiation protection officers necessary for the safe performance of the activity has been appointed and they have been granted the powers required to fulfil their duties.</li> <li>• it is ensured that the equipment is available and that the measures required according to the state of the art have been taken to ensure that the protective regulations are complied with.</li> </ul> </li> </ul>

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- Information that makes it possible to check whether the radiation protection manager and the radiation protection officers are reliable and have the necessary expertise in radiation protection.
- Copy of a radiation protection instruction in accordance with the legal ordinance pursuant to Section 73, if the issuance of a radiation protection instruction is required.
  - in connection with
    - for use in humans: information enabling it to be verified whether the requirements of Section 14(1) are met.
    - the use on animals in veterinary medicine: information that makes it possible to check whether the requirements of Section 15 are met.
    - the use of an X-ray device in teleradiology: information that makes it possible to check whether the requirements of Section 14 paragraph 2 are met.
    - the early detection of diseases: information that makes it possible to check whether the requirements of Section 14 Paragraph 3 Number 2 are met.

## Voraussetzungen

As the person responsible for radiation protection, you can submit the application.

You will receive approval if

- You have the necessary reliability and expertise in radiation protection
  - the necessary number of radiation protection officers have been appointed and they have been granted the necessary powers
  - other persons working there have the necessary knowledge and skills with regard to the possible radiation hazard and the protective measures to be applied
    - the necessary personnel are available
- You have the necessary equipment and have taken the necessary measures
  - it is a justified type of activity under a legal regulation or if, taking into account a published report, there are no significant doubts as to the justification of the type of activity
    - no other public law provisions conflict
    - the necessary provisions have been made to meet

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statutory liability for damages

- the necessary protection against disruptive measures or other influences by third parties is guaranteed
- when dealing with high-activity radioactive sources, appropriate emergency procedures and appropriate communication links are in place

You will receive approval for medical X-ray facilities if you also meet the following requirements:

- You or the person responsible for radiation protection have a license to practice medicine or dentistry or you are temporarily permitted to practice medicine or dentistry.
  - In the case of treatment with radioactive substances or ionizing radiation based on an individual radiation treatment plan, a medical physics expert can be called in to work closely with the patient.
  - In the case of treatment with radioactive substances or ionising radiation that is not based on an individual treatment plan (standardised treatment) and in the case of an examination with radioactive substances or ionising radiation that may involve significant exposure of the person being examined, a medical physics expert may be called in to assist.
  - For all other applications involving ionizing radiation or radioactive substances on humans, it is ensured that a medical physics expert can be consulted for advice, if the respective application requires it.
- The necessary equipment is available and the necessary measures have been taken to ensure the quality required for the application
  - in examinations with the lowest possible exposure.
  - for treatments with the dose distribution required for the intended purposes.

## Kosten

Fees apply. The amount of the fees depends on the administrative effort.

## Verfahrensablauf

- You complete the relevant application form in full and send it to the responsible authority, including the documents listed in the application.
  - The responsible authority will examine your

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	<p>application.</p> <ul style="list-style-type: none"> <li>• If necessary, the responsible authority will request further documents or information from you.</li> <li>• The responsible authority will decide on your application.</li> <li>• You will receive a notification.</li> <li>• The fee notice will usually be sent to you later.</li> <li>• If you have permission, you may use the X-ray facility.</li> </ul>
Bearbeitungsdauer	If all required documents are available, processing normally takes 4 weeks.
Frist	You need approval before you can operate the X-ray facility.
weiterführende Informationen	
Hinweise	No.
Rechtsbehelf	Objection within one month of receipt of the decision
Kurztext	<ul style="list-style-type: none"> <li>• Operation of an X-ray facility or significant change in operation Approval</li> <li>• Only the person responsible for radiation protection according to § 69 StrlSchG can submit the application</li> <li>• Approval or rejection notices are subject to a fee</li> <li>• Use the application form at <a href="https://www.hamburg.de/formulare/">https://www.hamburg.de/formulare/</a></li> </ul>
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Behördenfinder Hamburg, Authority finder Hamburg (Currently this link is only available in german)