

99009049006000

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/172092/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99009049006000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Installations for the production of ionizing radiation; application for a permit for operation or modification
Typisierung	2 - Bundesauftragsverwaltung: Regelung
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	14.10.2024

Modul	Sachverhalt
Fachlich freigegeben durch	Bayerisches Staatsministerium für Umwelt und Verbraucherschutz (Bavarian State Ministry of the Environment and Consumer Protection)
Handlungsgrundlage	https://www.gesetze-im-internet.de/strlschg/_12.html https://www.gesetze-im-internet.de/strlschg/_12.html https://www.gesetze-im-internet.de/strlschg/_13.html https://www.gesetze-im-internet.de/strlschg/_13.html https://www.gesetze-im-internet.de/strlschg/_14.html https://www.gesetze-im-internet.de/strlschg/_14.html https://www.gesetze-im-internet.de/strlschg/anlage_2.html https://www.gesetze-im-internet.de/strlschg/anlage_2.html
Teaser	The operation of a facility for the generation of ionizing radiation as well as the significant modification of the facility or its operation requires a permit and must be applied for with the competent authority.
Volltext	<p>The operation of facilities for the generation of ionizing radiation in connection with therapeutic use on humans (new approval) and the significant modification of a facility or its operation (modification approval) requires a permit.</p> <p>The Bavarian State Office for the Environment (LfU), as the competent authority, issues the operating license upon application. The documents and evidence required for the application for approval are regulated in the Radiation Protection Act (StrlSchG) and must be provided as part of the procedure.</p>
Erforderliche Unterlagen	<ul style="list-style-type: none"> • The following documents must be submitted: <ul style="list-style-type: none"> • Proof of acquisition of the required expertise in radiation protection <ul style="list-style-type: none"> • if acquired more than five years ago: current proof of updating the required specialist knowledge in radiation protection <ul style="list-style-type: none"> • for medical use: License to practice medicine • Radiation protection instruction • for companies: Extract from the commercial register or partnership register • for natural persons: Proof of reliability by means of

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a certificate of good conduct or form

- Floor plan with building and room plan
- Proof of the security concept, if applicable
- Proof of provisional cover

Voraussetzungen

Applications for approval of a facility for the generation of ionizing radiation can be submitted to the LfU by legal entities and natural persons who wish to operate a facility in Bavaria.

Important general licensing requirements:

- The handling site, for example the operating site where the radioactive substances or the device are to be used or stored, must be located in Bavaria. If you wish to use radioactive substances in a mobile manner, you or your institution must have your habitual residence or registered office in Bavaria.
- There are no facts that give rise to concerns about the reliability of the applicant or the person authorized to represent them.
- Appointment of radiation protection officers with the necessary expertise to perform the tasks and in sufficient numbers
- A sufficient number of personnel to carry out the activities safely
- Evidence of state-of-the-art technology and measures to comply with the protection regulations

Important additional special requirements for activities in connection with use on humans:

- License to practice medicine or dentistry (or permission to temporarily practice medicine or dentistry)
- Ensuring the availability of medical physics experts in defined treatments in sufficient numbers
- Proof of ensuring the lowest possible exposure during examinations or the dose distribution required for the intended purposes during treatments
- Further requirements also apply to the authorization for teleradiology

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Important additional special requirements for activities in connection with the use on animals in veterinary medicine:

- License to practice as a veterinarian, physician or dentist (or permission to temporarily practice as a veterinarian, physician or dentist)

All applicable application requirements are regulated in Sections 13 and 14 and Annex 2 Part B of the Radiation Protection Act (StrlSchG). In principle, the applicant is obliged to obtain information on the applicable legal requirements under the StrlSchG. **

Kosten

165.00 to 6500.00 EUR

Verfahrensablauf

The necessary documents must be submitted to the LfU together with the application for an operating license.

The application can be submitted informally by post and/or e-mail or electronically via the application for the operation of an ionizing radiation facility (see "Online procedure").

The LfU checks the documents for completeness and compliance with the licensing requirements and, if necessary, requests the submission of missing evidence.

If necessary, the LfU may involve experts in the assessment process.

After a positive review of the application and all documents, the LfU issues the permit to operate the ionizing radiation facility.

The decision will be sent by post by the LfU.

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Bearbeitungsdauer	6 weeks to 6 months
Frist	The application must be submitted in good time before the start of medical operations. Beam generation and delivery may only take place once a permit has been issued. This also applies to the first beam emission during planned inspections and maintenance of the accelerator (e.g. the acceptance test of the structural radiation protection by the expert), unless this is carried out within the framework of a locally valid approval of the manufacturer under his responsibility under radiation protection law.
weiterführende Informationen	https://www.lfu.bayern.de/strahlung/index.htm https://www.lfu.bayern.de/strahlung/index.htm
Hinweise	The examination of the structural requirements for radiation protection in accordance with DIN 6847-2 or DIN EN ISO 16645 as a prerequisite for approval is also examined by the LfU as part of the approval procedure. The LfU recommends contacting the authorities at an early stage and involving them in the planning process so that any structural requirements can be included in the construction planning.
Rechtsbehelf	An appeal against the decision may be lodged with the competent administrative court within one month of notification.
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal