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Notify or apply for the operation of a medical X-ray facility or a significant change to its operation

Heruntergeladen am 21.06.2025

<https://fimportal.de/xzufi-services/6011497/L100022>

Modul	Sachverhalt
Leistungsschlüssel	99006018006000
Leistungsbezeichnung I	Notify or apply for the operation of a medical X-ray facility or a significant change to its operation
Leistungsbezeichnung II	Notify or apply for the operation of a medical X-ray facility or a significant change to its operation
Typisierung	2 - Bundesauftragsverwaltung: Regelung
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	

Modul	Sachverhalt
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegeben durch	
Handlungsgrundlage	<p>Strahlenschutzgesetz (StrlSchG):</p> <ul style="list-style-type: none"> • § 12 Absatz 1 Nummer 4 und Absatz 2 Genehmigungsbedürftige Tätigkeiten • § 13 Allgemeine Voraussetzungen für die Erteilung der Genehmigung; Aussetzung des Genehmigungsverfahrens • § 14 Besondere Voraussetzungen bei Tätigkeiten im Zusammenhang mit der Anwendung am Menschen • § 15 Besondere Voraussetzungen bei Tätigkeiten im Zusammenhang mit der Anwendung am Tier in der Tierheilkunde • § 16 Erforderliche Unterlagen • § 19 Absatz 1, 2, 3 und 5 Genehmigungs- und anzeigebedürftiger Betrieb von Röntgeneinrichtungen • § 20 Prüfung des angezeigten Betriebs einer Röntgeneinrichtung
Teaser	<p>If you wish to operate an X-ray facility in human medicine, dentistry or veterinary medicine that requires a licence or wish to make significant changes to its operation, you must first apply for a licence from the competent authority for radiation protection. The competent authority will check the application and the documents submitted by you. If all requirements are met, you will receive a licence.</p>
Volltext	<p>If you wish to operate an X-ray facility in human medicine, dentistry or veterinary medicine that requires a licence or wish to make significant changes to its operation, you must first apply for a licence from the competent authority for radiation protection. The competent authority will check the application and the documents submitted by you. If all requirements are met, you will receive a licence.</p> <p>In the case of an X-ray facility in human medicine,</p>

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dentistry or veterinary medicine that does not require a licence, the planned commissioning or significant change in operation must be notified.

In addition to conventional X-ray equipment, X-ray equipment includes other types of equipment such as C-arms, computer tomographs, bone density measuring devices, mammography devices and X-ray therapy devices.

The operation of an X-ray device in connection with its use on humans must be reported immediately to a medical or dental centre designated by the competent authority.

Erforderliche Unterlagen

Depending on the individual case, the online application asks for the necessary information and specifies which supporting documents must be uploaded.

Documents required for a licence:

- Plans, drawings and descriptions of the structural and technical radiation protection equipment,
- Radiation protection instruction according to § 45 StrlSchV
- Proof that the number of radiation protection officers necessary for the safe performance of the activity has been appointed and that they have been granted the necessary authorisations to fulfil their duties, the equipment is available and measures have been taken that are necessary according to the state of the art to ensure compliance with the protection regulations, the person responsible for radiation protection and the radiation protection officers are reliable and have the necessary expertise in radiation protection,
- Information that makes it possible to check whether the special requirements for activities in connection with the use on humans according to § 14 StrlSchG or with the use on animals in veterinary medicine according to § 15 StrlSchG are fulfilled.

Documents required for notification:

- Test report and certificate from the expert

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- if applicable, authorisation certificate according to § 47 StrlSchG for the design of the X-ray equipment
- Plans, drawings of the structural and technical radiation protection equipment
- Proof that the number of radiation protection officers required for the safe operation of the X-ray equipment has been appointed and that they have been granted the necessary authorisation to fulfil their duties, each radiation protection officer has the necessary expertise or, if a radiation protection officer is not required, the person responsible for radiation protection, the authorised representative or the authorised radiation protection representative has the necessary expertise in radiation protection,
- Description of how the necessary knowledge and skills with regard to the possible radiation hazard and the protective measures to be applied are imparted to the persons otherwise working.
- Proof that the special requirements for activities in connection with the use of on humans in accordance with § 14 StrlSchG or on animals in veterinary medicine according to § 15 StrlSchG are fulfilled.

Voraussetzungen

For an authorisation:

- There are no concerns regarding the reliability of the person responsible for radiation protection or the person authorised to represent them and the appointed radiation protection officers.
- The number of radiation protection officers required for the safe performance of the activity has been appointed.
- The radiation protection officers have been granted the necessary powers to fulfil their duties.
- The radiation protection officers have the necessary expertise in radiation protection.
- If no radiation protection officer has been appointed, the person submitting the application has the necessary expertise in radiation protection.
- The personnel required for the safe performance of the activity are available.
- It is ensured that the persons working have the necessary knowledge and skills with regard to the possible radiation hazard and the protective measures to be applied.

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	<ul style="list-style-type: none"> • The equipment is available and the safety regulations are complied with. • It is a justified type of activity and there are no other public law regulations to the contrary. <p>For a notification:</p> <ul style="list-style-type: none"> • You are operating an X-ray facility that does not require a licence or you wish to significantly change its operation. • The documents required for this are enclosed with the notification.
Kosten	Between EUR 350 and EUR 5,000 for an authorisation, depending on the individual case Between EUR 230 and EUR 1,000 for a notification, depending on the individual case
Verfahrensablauf	<p>You can complete the application for authorisation of an X-ray facility in human medicine, dentistry or veterinary medicine (except teleradiology) or the notification online here by completing the online application and uploading the required evidence.</p> <p>You can also complete the application for authorisation of an X-ray facility in human medicine, dentistry or veterinary medicine (including teleradiology) or the notification in writing. You can find the appropriate pdf document on the joint homepage of the regional councils.</p> <p>The contact details of the medical or dental authority that must be notified immediately of the operation of an X-ray facility in connection with the use on humans are stated in the online application or in the pdf document.</p>
Bearbeitungsdauer	For an authorisation: no details For a notification: After the 4 weeks have elapsed, you may operate the X-ray equipment unless the competent authority has suspended the procedure in accordance with Section 20 (2) StrlSchG or prohibited operation in accordance with Section 20 (3) StrlSchG.
Frist	For an authorisation: Prior to the commissioning or significant modification of the operation of an X-ray

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	device requiring authorisation For a notification: At least 4 weeks before the planned commissioning or significant change to the operation of the X-ray equipment
weiterführende Informationen	
Hinweise	Authorisation for the operation of an X-ray facility for teleradiology cannot be applied for online. The appropriate pdf document for the written application can be found on the joint homepage of the regional councils.
Rechtsbehelf	Information on the options for appealing against the decision of the competent authority can be found in the decision of the authority.
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	