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Apply for approval for the operation of an X-ray facility or the significant modification of the operation for teleradiology

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/121298705/L100002>

Modul	Sachverhalt
Leistungsschlüssel	99006018001002, 99006018001002
Leistungsbezeichnung I	Apply for approval for the operation of an X-ray facility or the significant modification of the operation for teleradiology
Leistungsbezeichnung II	Apply for approval for the operation of an X-ray facility or the significant modification of the operation for teleradiology
Typisierung	2 - Bundesauftragsverwaltung: Regelung
Quellredaktion	Nordrhein-Westfalen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung

Modul	Sachverhalt
Leistungsgruppierung	Arbeitsschutz (006)
Verrichtungskennung	Erteilung (001)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Produkt- und Stoffzulassung (2120200), Anlagenbetrieb und -prüfung (2120100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	25.07.2024
Fachlich freigegeben durch	Ministry of Labor, Health and Social Affairs of the State of North Rhine-Westphalia
Handlungsgrundlage	<p>§ 19 paragraph 2 number 3, § 12 paragraph 1 number 4 Radiation Protection Act (StrlSchG)</p> <p>https://www.gesetze-im-internet.de/strlschg/_12.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_19.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_12.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_19.html</p>
Teaser	If you wish to operate a teleradiology X-ray facility or make significant changes to it, you must first apply for a permit from the competent authority.
Volltext	<p>The permit allows you to put a teleradiology X-ray system into operation or make significant changes to it. Before you receive the permit, the authority will check whether you have submitted all the necessary documents and whether the legal requirements are met. Changes to the persons responsible must also be reported again.</p> <p>Examples of other significant changes are</p> <ul style="list-style-type: none"> • a change of room, • the image receiver • or structural changes to the room.
Erforderliche Unterlagen	In addition to the main application for approval, the following documents must be submitted:

Modul

Sachverhalt

- 1\.. plans, drawings and descriptions required to check the licensing requirements,
 - 2\.. information that makes it possible to check whether
 - a) the number of radiation protection officers necessary for the safe performance of the activity has been appointed and whether they have been granted the powers necessary for the performance of their duties,
 - b) it is ensured that 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,
 - 3\.. information that makes it possible to check whether the person responsible for radiation protection and the radiation protection officers are reliable and have the necessary expertise in radiation protection,
 - 4\.. a copy of a radiation protection instruction if it is necessary to issue a radiation protection instruction,
- i.e. in particular:
- Proof of expertise in radiation protection including proof of updating
 - Certificate and test report on radiation protection testing of the device by an expert or an expert organization
 - Type approval certificate with confirmation of routine testing or CE certificate of conformity
 - Proof of knowledge of radiation protection for the personnel deployed, including updates to these certificates

Voraussetzungen

- Approval will be granted if the relevant requirements are met. The requirements are met if
1. there are no facts that give rise to concerns about the reliability of the applicant, his or her legal representative or, in the case of legal entities or associations of persons without legal capacity, the persons authorized to represent or manage them by law, articles of association or partnership agreement

Modul

Sachverhalt

and, if a radiation protection officer is not required, one of the aforementioned natural persons has the necessary expertise in radiation protection,

2. there are no facts that give rise to concerns about the reliability of the radiation protection officers and they have the necessary expertise in radiation protection,

3. the number of radiation protection officers necessary for the safe performance of the activity has been appointed and they have been granted the necessary powers to perform their duties,

4. it is ensured that the persons otherwise involved in the activity have the necessary knowledge and skills with regard to the possible radiation hazard and the protective measures to be applied,

5. there are no facts giving rise to doubts as to whether the personnel required to carry out the activity safely are available,

6. it is ensured that the equipment is available and the measures are taken which, in the case of an activity in accordance with § 12 paragraph 1 number 4, are necessary according to the state of the art so that the protective regulations are complied with,

7. it is not an unjustified type of activity in accordance with an ordinance pursuant to Section 6 (3) or if, taking into account a report published in accordance with Section 7 (2), there are no significant doubts as to the justification of the type of activity, and

8. other provisions of public law do not conflict with this.

Kosten

EUR 100 to 4,000

Verfahrensablauf

- As the operator of an X-ray machine, you must apply for a permit to operate it or for a significant change.
 - If it is a construction procedure, it may make sense to involve the radiation protection authority at an early stage.
 - The authority will first check your application for completeness. The second step is to check whether all requirements are met. Documents may be requested at a later stage.
 - The permit will be issued to you in writing.

Bearbeitungsdauer

2 - 4 Woche(n)

Modul	Sachverhalt
	If additional documents have to be requested and submitted, the processing time will be extended. up to 6 weeks
Frist	Before commissioning the X-ray equipment
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Action before the administrative court
Kurztext	<ul style="list-style-type: none"> • Operation of an X-ray facility or significant change to the operation Approval for teleradiology <ul style="list-style-type: none"> • Application for approval of the operation or significant modification of a teleradiology X-ray facility • Approval will be granted if the documents submitted are complete and the legal requirements are met • The application for approval must be submitted before the device is put into operation or the changes are made • Application in writing or online • Responsible: Department 55 of the respective district government
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Genehmigung für den Betrieb einer Röntgeneinrichtung oder die wesentliche Änderung des Betriebs zur Teleradiologie beantragen, Apply for approval for the operation of an X-ray facility or the significant modification of the operation for teleradiology