

99006018261001, 99006018261001

Operation of an X-ray facility or significant change to the operation Acceptance for dental, medical or veterinary X-ray facilities

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/389480552/L100001>

Modul	Sachverhalt
Leistungsschlüssel	99006018261001, 99006018261001
Leistungsbezeichnung I	Operation of an X-ray facility or significant change to the operation Acceptance for dental, medical or veterinary X-ray facilities
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arbeitsschutz (006)

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Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Anmeldepflichten (2010100), Prüfung und Nachweise für Sachkunde und Sicherheit (2120300), Anlagenbetrieb und -prüfung (2120100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	31.01.2024
Fachlich freigegeben durch	Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV)
Handlungsgrundlage	https://www.gesetze-im-internet.de/strlsg/_19.html https://www.gesetze-im-internet.de/strlsg/_19.html
Teaser	Do you want to operate dental, medical or veterinary X-ray equipment or make significant changes to it? Then you must notify the competent authority for radiation protection.
Volltext	Even if your dental, medical or veterinary X-ray equipment is not subject to approval, you must notify the competent authority for radiation protection in writing if you wish to operate the equipment or make significant changes to it or its operation. Significant changes to an X-ray facility can be, for example • Change of room • Structural changes to the room • Change of the image receiver
Erforderliche Unterlagen	• Proof of expertise in radiation protection in accordance with § 74 Radiation Protection Act in conjunction with § 47 Radiation Protection Ordinance. § 47 Radiation Protection Ordinance with proof of updating • Certificate and test report from experts on the radiation protection test • Proof of knowledge of radiation protection and of

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	updates to this knowledge for personnel working at the X-ray facilities If necessary, you must also submit • Type approval certificate with confirmation of routine testing • CE certificate of conformity
Voraussetzungen	• You would like to operate an X-ray system, • whose X-ray source is type-approved. • whose manufacture and use falls under the Medical Devices Act. • which is used for the first time as a medical device and is not used in connection with medical exposures. • Or you wish to make significant changes to dental, medical or veterinary X-ray equipment.
Kosten	
Verfahrensablauf	
Bearbeitungsdauer	2 - 4 Woche(n) If additional documents have to be requested and submitted, the processing time will be extended.
Frist	You must submit the documents to the competent authority for radiation protection before commissioning the X-ray equipment and report the planned operation.
weiterführende Informationen	
Hinweise	There are no indications or special features.
Rechtsbehelf	
Kurztext	• Operation of an X-ray facility or significant change in operation Receipt for dental, medical or veterinary X-ray facilities • Companies with dental, medical or veterinary X-ray facilities must notify the competent authority if • they wish to put the X-ray equipment into operation for the first time

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- wish to make significant changes to the operation of the X-ray equipment, e.g:
 - change of room
 - structural changes to the room
 - change of the image receiver
- Notification must be made even if the X-ray equipment is not subject to approval
- The following documents are required for notification:
 - Proof of expertise in radiation protection with proof of updating
 - Certificate and test report from the expert on the radiation protection test
 - Proof of knowledge of radiation protection and of updates to this knowledge for the personnel working on the X-ray equipment
 - Type approval certificate with confirmation of routine testing, if applicable
 - CE certificate of conformity, if applicable
- Notification must be made in writing
- Responsible: competent authority for radiation protection

Ansprechpunkt
Zuständige Stelle
Formulare
Ursprungsportal

Operation of an X-ray facility or significant change to the operation Acceptance for dental, medical or veterinary X-ray facilities, Betrieb einer Röntgeneinrichtung oder wesentliche Änderung des Betriebs Entgegennahme für zahnmedizinische, medizinische oder tiermedizinische Röntgeneinrichtungen