

99006018001003, 99006018001003

# Display operation or significant change in operation of dental, medical and veterinary X-ray equipment

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/395451010/L100001>

Modul	Sachverhalt
Leistungsschlüssel	99006018001003, 99006018001003
Leistungsbezeichnung I	Display operation or significant change in operation of dental, medical and veterinary X-ray equipment
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arbeitsschutz (006)

Modul	Sachverhalt
Verrichtungskennung	Erteilung (001)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Anlagenbetrieb und -prüfung (2120100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	27.09.2023
Fachlich freigegeben durch	Hessian Ministry for the Environment, Climate Protection, Agriculture and Consumer Protection (HMuKLV) Department II 8 "Radiation protection, large accelerators, emergency protection"
Handlungsgrundlage	<a href="https://www.gesetze-im-internet.de/strlschg/_19.html">https://www.gesetze-im-internet.de/strlschg/_19.html</a> <a href="https://www.gesetze-im-internet.de/strlschg/_19.html">https://www.gesetze-im-internet.de/strlschg/_19.html</a>
Teaser	If you intend to operate an X-ray facility for which notification is sufficient in accordance with Section 19 (1) or to make significant changes to it, you are obliged to notify the competent authority of this at least four weeks before the intended start.
Volltext	<p>If you intend to operate an X-ray facility in accordance with Section 19 (1) or plan to make significant changes to the operation of an existing and notified X-ray facility, you must notify the competent authority. The competent authority must be notified in writing at least four weeks before the intended start. After expiry of this period, the notifying party may operate the X-ray facility unless the authority suspends the procedure or prohibits operation.</p> <p>The holder of a notification may be a partnership with legal capacity, a legal entity or a natural person. The notification always refers to the person responsible for radiation protection. If there are changes in the radiation protection organization, please contact the competent authority to discuss or arrange further steps.</p>
Erforderliche Unterlagen	The list of documents required for notification in accordance with Section 19 (1) can be found in Section 19 (3) of the Act on Protection against the Harmful

## Modul

## Sachverhalt

Effects of Ionizing Radiation (StrlSchG)

In particular

- Proof of expertise and, if necessary, updates for the radiation protection officer if no radiation protection officer is available
- Proof of expertise and, if necessary, updates for the radiation protection officer
- Certificate and the expert test report in accordance with SV RL Röntgen
- Floor plan sketch of the X-ray room and adjacent rooms
- Type approval

## Voraussetzungen

You either want

- 1\ operate an X-ray device
  - a) whose X-ray source is type-approved in accordance with § 45 paragraph 1 number 2,
  - b) the manufacture and first placing on the market of which falls within the scope of the Medical Devices Act, or
  - c) whose manufacture and placing on the market falls within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1; L 117, 3.5.2019, p. 9; L 334, 27.12.2019, p. 165),
  - (d) which has been placed on the market for the first time in accordance with the provisions of the Medical Devices Act and is not used in connection with medical exposures; or
  
- 2\ you wish to operate a basic, high or full protection device or a school X-ray device; or
  
- 3\ you wish to significantly change the operation of such a notified X-ray device and you have a license in

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	accordance with §15 StrISchG.
Kosten	Verwaltungsgebühr: 200€ Method of payment: Bank transfer <a href="https://www.rv.hessenrecht.hessen.de/bshe/document/jlr-UmwMinVwKostOHE2009rahmen/part/X">https://www.rv.hessenrecht.hessen.de/bshe/document/jlr-UmwMinVwKostOHE2009rahmen/part/X</a>
Verfahrensablauf	<ul style="list-style-type: none"> <li>• You submit a written notification to the competent authority. In it, you declare whether you are operating or significantly modifying dental, medical and veterinary X-ray equipment.             <ul style="list-style-type: none"> <li>• The notification must be submitted before the X-ray equipment is put into operation or significantly modified.</li> <li>• The competent authority will check the documents and send you a notification confirmation with a fee notice.</li> </ul> </li> </ul>
Bearbeitungsdauer	4 Woche(n) Depending on the scope of the application and completeness of the documents. Usually within 4 weeks
Frist	4 Woche(n) before commissioning the X-ray equipment
weiterführende Informationen	
Hinweise	The following information is available: Notification must be obtained before the X-ray equipment is put into operation. The same applies to the planning of significant changes. <a href="https://landwirtschaft.hessen.de/Umwelt/Kernenergie-und-Strahlenschutz/Strahlenschutz">https://landwirtschaft.hessen.de/Umwelt/Kernenergie-und-Strahlenschutz/Strahlenschutz</a> <a href="https://landwirtschaft.hessen.de/Umwelt/Kernenergie-und-Strahlenschutz/Strahlenschutz">https://landwirtschaft.hessen.de/Umwelt/Kernenergie-und-Strahlenschutz/Strahlenschutz</a>
Rechtsbehelf	
Kurztext	\- Operation of a notifiable X-ray device or a significant change to its operation  \- Operation of an X-ray facility: notify in writing at least four weeks before the intended start.

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	<p>\- The owner may be a partnership with legal capacity, a legal entity or a natural person.</p> <p>\- Responsible: Regional Councils, Environment Department</p>
Ansprechpunkt	Regional Councils, Environment Department
Zuständige Stelle	<ul style="list-style-type: none"> <li>• Darmstadt Regional Council</li> </ul> <p>Department Environment Darmstadt</p> <p>Department IV / Da 43.1 - Radiation protection, immission control (surface treatment, storage facilities)</p> <ul style="list-style-type: none"> <li>• Darmstadt Regional Council</li> </ul> <p>Department Environment Frankfurt</p> <p>Department IV/F 43.3 - Radiation protection, chemicals legislation</p> <ul style="list-style-type: none"> <li>• Darmstadt Regional Council</li> </ul> <p>Environment Department Wiesbaden</p> <p>IV/Wi 43.1 - Radiation protection, immission control (metal)</p> <ul style="list-style-type: none"> <li>• Regional Council Giessen</li> </ul> <p>Department IV Environment</p> <p>Department 44.2 Genetic Engineering and Radiation Protection</p> <ul style="list-style-type: none"> <li>• Regional Council Kassel</li> </ul>

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	<p>Department III Environmental Protection</p> <p>Department 33.1 Immission and Radiation Protection</p>
Formulare	<p>Forms available: Yes</p> <p>Written form required: Yes</p> <p>Informal application possible: No</p> <p>Personal appearance necessary: No</p>
Ursprungsportal	<p>Betrieb oder wesentliche Änderung des Betriebs einer zahnmedizinischen, medizinischen und tiermedizinischen Röntgeneinrichtung anzeigen, Display operation or significant change in operation of dental, medical and veterinary X-ray equipment</p>