

99006018006000

Heruntergeladen am 21.06.2025

<https://fimportal.de/xzufi-services/S1000020010000012053/S100002>

Modul	Sachverhalt
Leistungsschlüssel	99006018006000
Leistungsbezeichnung I	
Leistungsbezeichnung II	
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	<div lang="en-x-mtfrom-de">Registering an X-ray machine without a CE mark</div>, <div lang="en-x-mtfrom-de">Approval for X-ray</div>, <div lang="en-x-mtfrom-de">Report change to X-ray machine</div>
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	

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Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	15.08.2022
Fachlich freigegeben durch	
Handlungsgrundlage	§ 12 paragraph 1 number 4 and paragraph 2 StrlSchG
Teaser	
Volltext	
Erforderliche Unterlagen	<ul style="list-style-type: none"> • Plans, drawings and descriptions required to verify the approval requirements • Information that makes it possible to check whether the number of radiation protection officers necessary for the safe performance of the activity has been appointed and they have been granted the powers required to fulfil their duties. it is ensured that the equipment is available and that the measures required according to the state of the art have been taken to ensure that the protective regulations are complied with. • Information that makes it possible to check whether the radiation protection manager and the radiation protection officers are reliable and have the necessary expertise in radiation protection. • Copy of a radiation protection instruction in accordance with the legal ordinance pursuant to Section 73, if the issuance of a radiation protection instruction is required. • in connection with for use in humans: information enabling it to be verified whether the requirements of Section 14(1) are met. the use on animals in veterinary medicine: information that makes it possible to check whether the requirements of Section 15 are met. the use of an X-ray device in teleradiology: information that makes it possible to check whether the requirements of Section 14 paragraph 2 are met. the early detection of diseases: information that makes it possible to check whether the requirements of Section 14 Paragraph 3 Number 2 are met.
Voraussetzungen	<ul style="list-style-type: none"> • You have the necessary reliability and expertise in radiation protection

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- the necessary number of radiation protection officers have been appointed and they have been granted the necessary powers
 - other persons working there have the necessary knowledge and skills with regard to the possible radiation hazard and the protective measures to be applied
 - the necessary personnel are available
 - You have the necessary equipment and have taken the necessary measures
 - it is a justified type of activity under a legal regulation or if, taking into account a published report, there are no significant doubts as to the justification of the type of activity
 - no other public law provisions conflict
 - the necessary provisions have been made to meet statutory liability for damages
 - the necessary protection against disruptive measures or other influences by third parties is guaranteed
 - when dealing with high-activity radioactive sources, appropriate emergency procedures and appropriate communication links are in place
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- You or the person responsible for radiation protection have a license to practice medicine or dentistry or you are temporarily permitted to practice medicine or dentistry.
 - In the case of treatment with radioactive substances or ionizing radiation based on an individual radiation treatment plan, a medical physics expert can be called in to work closely with the patient.
 - In the case of treatment with radioactive substances or ionising radiation that is not based on an individual treatment plan (standardised treatment) and in the case of an examination with radioactive substances or ionising radiation that may involve significant exposure of the person being examined, a medical physics expert may be called in to assist.
 - For all other applications involving ionizing radiation or radioactive substances on humans, it is ensured that a medical physics expert can be consulted for advice, if the respective application requires it.
 - The necessary equipment is available and the

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	necessary measures have been taken to ensure the quality required for the application in examinations with the lowest possible exposure. for treatments with the dose distribution required for the intended purposes.
Kosten	
Verfahrensablauf	<ul style="list-style-type: none"> • You complete the relevant application form in full and send it to the responsible authority, including the documents listed in the application. • The responsible authority will examine your application. • If necessary, the responsible authority will request further documents or information from you. • The responsible authority will decide on your application. • You will receive a notification. • The fee notice will usually be sent to you later. • If you have permission, you may use the X-ray facility.
Bearbeitungsdauer	
Frist	
weiterführende Informationen	
Hinweise	
Rechtsbehelf	
Kurztext	<ul style="list-style-type: none"> • Operation of an X-ray facility or significant change in operation Approval • Only the person responsible for radiation protection according to § 69 StrlSchG can submit the application • Approval or rejection notices are subject to a fee • Use the application form at https://www.hamburg.de/formulare/
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link

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is only available in german)