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Bauartzulassung für Geräte und anderen Vorrichtung in die sonstige radioaktive Stoffe eingefügt sind, sowie von Anlagen zur Erzeugung ionisierender Strahlen Erteilung

Heruntergeladen am 13.07.2025

<https://fimportal.de/xzufi-services/101180131/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99009018001000
Leistungsbezeichnung I	Bauartzulassung für Geräte und anderen Vorrichtung in die sonstige radioaktive Stoffe eingefügt sind, sowie von Anlagen zur Erzeugung ionisierender Strahlen Erteilung
Leistungsbezeichnung II	Apply for type approval for devices with radioactive substances and systems for generating ionizing radiation
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus

Modul	Sachverhalt
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Erteilung (1)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Anlagenbetrieb und -prüfung (2120100), Abfall, Schadstoffe und Emissionen (2130100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	01.09.2020
Fachlich freigegeben durch	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU)
Handlungsgrundlage	https://www.gesetze-im-internet.de/strlschg/BJNR196610017.html https://www.gesetze-im-internet.de/strlschv_2018/BJNR203600018.html
Teaser	If you want to manufacture devices with radioactive substances or systems for generating ionizing radiation that may be operated without a permit or notification, you can apply for a type approval.
Volltext	The Federal Office for Radiation Protection (BfS) is responsible for issuing type approvals for devices with radioactive substances and systems for generating ionizing radiation. If you obtain a type approval for a device or system, you can use it without approval or notification. By issuing the type approval, the BfS confirms that the tested type meets the legal requirements for radiation protection. The type approval covers the entire type. No special approval or testing is required for individual devices. You submit your application for type approval for devices in which radioactive substances are inserted

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and for systems for generating ionizing radiation to the BfS.

Please note: The BfS issues the type approval for a maximum of 10 years. You can apply to have a type approval extended.

Erforderliche Unterlagen

You must submit the following with your application

- Description of the design of the device and its application
- Drawings (compilations, possibly exploded views) with associated material specifications, in particular for shielding and source holders
- Information on the emitter, in particular drawings of the emitter and information on the beam classification in accordance with DIN EN ISO 2919, certificates or information on the USP laser with performance data
- Information on permissible operating conditions and the intended duration of use
- Operating instructions in German
- Quality control concept
- Return concept
- Current extract from the commercial register
- Certificate of good conduct for submission to the authorities by the persons representing the applicant (e.g. management)
- Proof of qualification of the technical production manager
- Proof of qualification of the experts to be appointed for quality control during production
- Form for administrative information
- Depending on the application: form for devices or form for systems

Voraussetzungen

Applications for approval can be submitted by

- legal persons who place a device or system on the market in Germany manufacturers or Persons and organizations who deliver the device or system to Germany or have it delivered to Germany

Further requirements:

- You must carry out quality control to ensure that only

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devices that comply with the tested type are manufactured or shipped to Germany

- The quality control must be supervised by an expert

Kosten

The Federal Office for Radiation Protection (BfS) and, if applicable, the Federal Institute for Materials Research and Testing (BAM) charge costs for processing your application for type approval.

- BfS: between EUR 2,000 and EUR 9,000, depending on the effort involved
- BAM: between EUR 1,000 and EUR 3,000, depending on expenditure

An advance payment may be required under special circumstances.

Verfahrensablauf

You must submit the application for type approval in writing to the Federal Office for Radiation Protection (BfS).

- You download the application forms from the BfS website and fill them in.
- You must select one or more experts to supervise the quality control. Experts are persons who have knowledge and experience in radiation protection as well as knowledge of the design and construction of the device in question. They may belong to their own or other companies (e.g. TÜV) and must be independent in the performance of their duties. Experts monitor that no device is placed on the market whose design deviates from the required approval. You must inform the BfS of the experts and their qualifications when submitting the application.
- Send the completed and signed application forms together with the other required documents to the BfS by post, fax or e-mail. You can send further documents by e-mail or via a file transfer portal and the BfS will check your application. For devices containing radioactive substances, the Federal Institute for Materials Research and Testing (BAM) will be involved.
- If all requirements are met, the BfS issues the type approval and awards a type mark. The approval certificate and the designation of the experts will be sent to you by post with a notification from the BfS.

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Bearbeitungsdauer	within 12 months
Frist	none
weiterführende Informationen	https://www.bfs.de/DE/themen/ion/anwendung-alltag/bauartzulassungen/bfs-strschv/strlschv-hinweise.html https://www.bfs.de/SharedDocs/Downloads/BfS/DE/unterlagen/baz-strlschv/antragsunterlagen/s-anforderungen.pdf?__blob=publicationFile&v=1 https://www.bfs.de/DE/themen/ion/anwendung-alltag/bauartzulassungen/bfs-strschv/strlschv-sachverstaendige.html
Hinweise	
Rechtsbehelf	
Kurztext	• Type approval for equipment and other devices in which other radioactive substances are incorporated and for systems for the generation of ionizing radiation - Issuing • Type approval involves checking whether the design and properties of a device have a sufficiently high safety level. This means that it can be operated without approval and in some cases without notification • The design of devices with radioactive substances and systems for generating ionizing radiation must be approved. These devices and systems can then be operated under simplified conditions without additional radiation protection requirements • The approval covers the entire design. Special approval or testing by the Federal Office for Radiation Protection (BfS) is no longer required for individual devices • Applications for approval can be submitted by legal persons who place a device or system on the market in Germany manufacturers or Persons and organizations who supply the device or system to Germany or have it supplied to Germany • Information by: Federal Office for Radiation Protection (BfS) • responsible: Federal Office for Radiation Protection (BfS)
Ansprechpunkt	

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Zuständige Stelle	
Formulare	https://www.bfs.de/SharedDocs/Downloads/BfS/DE/unterlagen/baz-strlschv/antragsunterlagen/s4.pdf?__blob=publicationFile&v=6 https://www.bfs.de/SharedDocs/Downloads/BfS/DE/unterlagen/baz-strlschv/antragsunterlagen/s4.pdf?__blob=publicationFile&v=6 https://www.bfs.de/SharedDocs/Downloads/BfS/DE/unterlagen/baz-strlschv/antragsunterlagen/s5-vorrichtungen.pdf?__blob=publicationFile&v=1 https://www.bfs.de/SharedDocs/Downloads/BfS/DE/unterlagen/baz-strlschv/antragsunterlagen/s5-anlagen.pdf?__blob=publicationFile&v=6
Ursprungsportal	Bauartzulassung für Geräte und anderen Vorrichtung in die sonstige radioaktive Stoffe eingefügt sind, sowie von Anlagen zur Erzeugung ionisierender Strahlen Erteilung, Bauartzulassung für Geräte und anderen Vorrichtung in die sonstige radioaktive Stoffe eingefügt sind, sowie von Anlagen zur Erzeugung ionisierender Strahlen Erteilung