

99009025261000

Mitteilung bei der Anwendung radioaktiver Stoffe oder ionisierender Strahlung zum Zweck der medizinischen Forschung Entgegennahme

Heruntergeladen am 06.06.2025

<https://fimportal.de/xzufi-services/102363785/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99009025261000
Leistungsbezeichnung I	Mitteilung bei der Anwendung radioaktiver Stoffe oder ionisierender Strahlung zum Zweck der medizinischen Forschung Entgegennahme
Leistungsbezeichnung II	Report termination, discontinuation or interruption of a medical study involving the use of radiation and other changes requiring notification
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	

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Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Gesundheits- und Sicherheitsvorschriften im Zusammenhang mit verschiedenen Arten von Tätigkeiten, einschließlich der Risikovermeidung, Information und Ausbildung
Lagen Portalverbund	Erlaubnisse und Genehmigungen für Forschungsvorhaben (2100200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	26.09.2022
Fachlich freigegeben durch	Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV)
Handlungsgrundlage	https://www.gesetze-im-internet.de/strlsv_2018/_141.html
Teaser	As a person authorized to conduct medical research, you must inform the Federal Office for Radiation Protection (BfS) of certain events relating to the use of radioactive substances and/or ionizing radiation on humans in the course of your research project.
Volltext	If you, as a person authorized to conduct medical research, are in charge of a study in which radioactive substances and/or ionizing radiation are used on humans ("radiation application"), you must inform the BfS about the following procedures: • the termination of the research project, • the discontinuation of the study-related use of radioactive substances and/or ionizing radiation, • an interruption of the study-related use of radioactive substances and/or ionizing radiation, • resumption after the interruption of the study-related use of radioactive substances and/or ionizing radiation, in the case of approved uses, the

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existence of significant new findings on the benefits associated with the research project, taking into account the medical benefit for the persons included, if applicable, or on radiation-related risks,

- in the case of multi-center studies, the resignation of a person responsible for radiation protection, and
- in the case of notified applications, a change with regard to the proof of the required coverage.

With the notification of termination, the permit for the further use of radioactive substances and/or ionizing radiation on humans for the purpose of medical research ceases to be valid. For those involved, this means that from this point onwards, no further study-related applications may be carried out as part of this research project.

If a notification concerns a significant change to notified or approved uses of radioactive substances and/or ionizing radiation in humans for the purpose of medical research, this may result in a chargeable amendment procedure.

Erforderliche Unterlagen

- Notifications can be made informally. You can fulfill your notification obligations by completing the forms provided by the BfS.
- If applicable, current proof of the required cover for notified applications in accordance with Section 32 (3) of the Radiation Protection Act in conjunction with Section 35 of the Radiation Protection Act.

Voraussetzungen

- You are an authorized person for medical research.
- The research project is terminated.
- The use of radioactive substances and/or ionizing radiation in your research project is discontinued or interrupted to protect the persons involved in the research project from radiation effects or due to a change in the risk-benefit ratio.
- In the case of an approved application: there are significant new findings on the benefits associated with the research project or on radiation-related risks.
- In the case of a multicenter study: A person responsible for radiation protection (a participating

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	center) drops out. • In the case of a notified application: There is a change with regard to the proof of the required coverage.
Kosten	There are generally no costs for processing the notifications. If necessary, notifications may result in an amendment procedure, for which fees will then be charged.
Verfahrensablauf	You report events in connection with approved and notified study-related radiation applications for medical research to the BfS without delay. You go to the BfS website. • You fill in the form "Cancellation, interruption or termination notification" to report the following: • the termination, • the discontinuation, • the interruption of the research project or • the resumption. • Notification of the departure of persons responsible for radiation protection in the case of multi-center studies is made in the "Other information on changes" section of the "Change application / notification of change" form. • The notification of a change with regard to the proof of the required coverage for notified applications is made in the Change notification form under "Notification of changes". • Send the completed form to the BfS by e-mail or post. • The BfS will assess the information. • In the case of the termination notification, the procedure is completed and kept until the end of the retention period. • Notifications of termination, interruption or the existence of new findings are evaluated by experts. If necessary, the further procedure is discussed with the person authorized to conduct medical research. • Notification of a change with regard to the proof of the required cover for notified applications generally leads to an amendment procedure.

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Information on the approval and notification procedures can be found on the BfS website. A free information event for applicants is usually held every year in the fall.

The BfS provides information about the date and the program on its website in good time before the respective information event. Interested parties are welcome to send an e-mail to: Veranstaltungen.MedForsch@BfS.de to register for a specific date.

Bearbeitungsdauer

The notifications are usually processed immediately.

Frist

The person authorized to conduct medical research must make the notification immediately, i.e. without undue delay.

weiterführende Informationen

https://www.bfs.de/DE/themen/ion/anwendung-medizin/forschung/forschung_node.html

Hinweise
Rechtsbehelf
Kurztext

- Notification of the use of radioactive substances or ionizing radiation for the purpose of medical research Acceptance
- Notifiable events in connection with the approved use of radioactive substances and/or ionizing radiation in humans for the purpose of medical research must be reported immediately.
- This includes
 - termination of the research project
 - discontinuation of the study-related use of radioactive substances and/or ionizing radiation
 - the interruption of the study-related use of radioactive substances and/or ionizing radiation,
 - resumption after the interruption of the study-related use of radioactive substances and/or ionizing radiation, in the case of approved uses, the existence of significant new findings on the benefits associated with the research project or on

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	radiation-related risks, • in the case of multi-center studies, the resignation of a person responsible for radiation protection, and • in the case of notified applications, a change with regard to the proof of the necessary precautionary coverage. • Responsible: Federal Office for Radiation Protection (BfS)
Ansprechpunkt	
Zuständige Stelle	
Formulare	Forms available: Yes Written form required: No Informal notification possible: Yes Personal appearance necessary: No Online services available: No
Ursprungsportal	Mitteilung bei der Anwendung radioaktiver Stoffe oder ionisierender Strahlung zum Zweck der medizinischen Forschung Entgegennahme, Mitteilung bei der Anwendung radioaktiver Stoffe oder ionisierender Strahlung zum Zweck der medizinischen Forschung Entgegennahme