

99009025261000

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

Heruntergeladen am 26.06.2025

<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       |                                                                                                                                                |

| Modul                         | Sachverhalt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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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            | <a href="https://www.gesetze-im-internet.de/strlschv_2018/_141.html">https://www.gesetze-im-internet.de/strlschv_2018/_141.html</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 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                      | <p>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:</p> <ul style="list-style-type: none"> <li>• the termination of the research project,</li> <li>• the discontinuation of the study-related use of radioactive substances and/or ionizing radiation,</li> <li>• an interruption of the study-related use of radioactive substances and/or ionizing radiation,</li> <li>• resumption after the interruption of the study-related use of radioactive substances and/or ionizing radiation,</li> </ul> <p>in the case of approved uses, the existence of</p> |

## Modul

## Sachverhalt

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 center) drops out.
- In the case of a notified application: There is a change

| Modul                   | Sachverhalt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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|                         | with regard to the proof of the required coverage.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Kosten</b>           | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Verfahrensablauf</b> | <p>You report events in connection with approved and notified study-related radiation applications for medical research to the BfS without delay.</p> <p>You go to the BfS website.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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".</li> <li>• Send the completed form to the BfS by e-mail or post.</li> <li>• The BfS will assess the information.</li> <li>• In the case of the termination notification, the procedure is completed and kept until the end of the retention period.</li> <li>• 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.</li> <li>• Notification of a change with regard to the proof of the required cover for notified applications generally leads to an amendment procedure.</li> </ul> <p>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.</p> <p>The BfS provides information about the date and the</p> |

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|                              | <p>program on its website in good time before the respective information event. Interested parties are welcome to send an e-mail to: <a href="mailto:Veranstaltungen.MedForsch@BfS.de">Veranstaltungen.MedForsch@BfS.de</a> to register for a specific date.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 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 | <a href="https://www.bfs.de/DE/themen/ion/anwendung-medizin/forschung/forschung_node.html">https://www.bfs.de/DE/themen/ion/anwendung-medizin/forschung/forschung_node.html</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Hinweise                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Rechtsbehelf                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Kurztext                     | <ul style="list-style-type: none"> <li>• Notification of the use of radioactive substances or ionizing radiation for the purpose of medical research</li> <li>Acceptance</li> <li>• 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.</li> <li>• 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 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.</li> <li>• Responsible: Federal Office for Radiation Protection (BfS)</li> </ul> |
| Ansprechpunkt                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Zuständige Stelle            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

| Modul           | Sachverhalt                                                                                                                                                                                                                                                                                          |
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| Formulare       | <p>Forms available: Yes Written form required: No<br/> Informal notification possible: Yes Personal<br/> appearance necessary: No</p> <p>Online services available: No</p>                                                                                                                           |
| Ursprungsportal | <p>Mitteilung bei der Anwendung radioaktiver Stoffe oder<br/> ionisierender Strahlung zum Zweck der medizinischen<br/> Forschung Entgegennahme, Mitteilung bei der<br/> Anwendung radioaktiver Stoffe oder ionisierender<br/> Strahlung zum Zweck der medizinischen Forschung<br/> Entgegennahme</p> |