Application submission, authorisation and notification procedure for human research projects involving radiation sources

**Procedure for:**
Clinical trials with therapeutic products capable of emitting ionising radiation

**Radiation source as a component of a medicinal product (radiopharmaceuticals)**
Category B trials

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**Application**
- **Application submission**
  - Category B
    - Use not according to marketing authorisation
  - **Project start**
    - Authorisation

**Ethics committee**
- **Application**
- **Formal examination**
- **Confirmation**
- **Evaluation of scientific, legal and ethical aspects**
  - 7 days
- **Notification of decision**

**Swissmedic**
- **Application**
- **Formal examination**
  - 7 days
- **Confirmation**
- **Examination of safety and quality of medicinal products and medical devices, observance of the Radiological Protection Act (incl. dose estimate)**

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**Authorisation phase**
- **Notification of decision**
- **Approval, revoke of approval, suspension**
- **Changes, notifications and reporting**
  - Approval, revoke of approval, suspension
- **Communication**
- **Assessment**
  - Approval, revoke of approval, suspension

**Implementation phase**
- **Evaluation of scientific, legal and ethical aspects**
- **Communication**
- **Assessment**

**Final phase**
- **Final report**
- **Archiving**

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**Relevant legal texts:**

- Authorisation phase
  - Art. 28 RPO (Dose limit)

- Implementation phase
  - Art. 29, 34 ClinO

- Final phase
  - Art. 38 ClinO