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

Procedure for:

Human research projects (with the exception of clinical trials)

Concomitant examinations with radiation sources
Projects, in which Art. 19 para. 2 HRO is not applicable

Applicant

Application submission

- Studies with an effective dose < 5 mSv
  - with sealed or unsealed radioactive sources or
- Studies with an effective dose < or > 5 mSv
  - and with units (RX\textsuperscript{1}, BES\textsuperscript{2}) or with authorised RPH\textsuperscript{3}
  - for nuclear medical routine examinations

Project start

Ethics committee

Formal examination

7 days

Examining scientific, legal and ethical aspects; observance of the Radiological Protection Act (incl. dose estimate)

Confirm application

FOPH

Project execution

Communication

Changes, notifications and reporting

Assessment

Approval, revoke of approval, suspension

Project completion

Communication

Archiving

Final phase

Final report

Notice

Exception: No final report to the FOPH for nuclear medical routine examinations with authorised RPH\textsuperscript{3} or with units (RX\textsuperscript{1}, BES\textsuperscript{2})

Relevant legal texts:

Authorisation phase

- Art. 14–16, 19 HRO
- Art. 28 RPO (Dose limit)

Implementation phase

- Art. 18, 20, 21 HRO

Final phase

- Art. 22, 23 HRO

\textsuperscript{1} RX: X-rays
\textsuperscript{2} BES: imaging with accelerators
\textsuperscript{3} RPH: radiopharmaceuticals