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 applicable

**Relevant legal texts:**

Authorisation phase
Art. 14–16, 19 HRO

Implementation phase
Art. 18, 20, 21 HRO

Final phase
Art. 22, 23 HRO

**Application submission**

Studies with an effective dose > 5 mSv and with unauthorised RPH\(^3\) or with authorised RPH\(^3\) for non-nuclear medical routine examinations or with other sealed or open radioactive radiation sources

**Project start**

Examining the observance of the Radiological Protection Act (incl. dose estimate)

**Authorisation**

Evaluation of scientific, legal and ethical aspects

**Application**

Formal examination

7 days

**Confirmation**

Evaluation of scientific, legal and ethical aspects

**Opinion**

**Project execution**

Changes, notifications and reporting

Communication

Assessment

Approval, revoke of approval, suspension

**Project completion**

Communication

Archiving

Communication

**FOPH**

Examining the observance of the Radiological Protection Act (incl. dose estimate)

**Notice**

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

1 RX: X-rays
2 BES: imaging with accelerators
3 RPH: radiopharmaceuticals