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 C trials

Relevant legal texts:
Authorisation phase
Art. 28 RPO (Dose limit)
Implementation phase
Art. 29, 34, 36 ClinO
Final phase
Art. 36, 38 ClinO

Swissmedic obtains opinion of FOPH for approval
1 Pursuant to Art. 36 ClinO Swissmedic may approve, insofar as the FOPH has no objection.

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