



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs
Federal Office of Public Health FC
Consumer Protection Directorate
Radiation Protection Division



Implementation of the new BSS in Switzerland

Nicolas Stritt
Swiss Federal Office of Public health
Radiation protection division

ERPAN, Paris meeting 2017

09. June 2017



Outlook

- Revision of the Swiss legislation
 - Scope of the revision
 - Main changes
 - Medical field
 - Exposed workers and dosimetry
 - New Liberation Limit (LL)
 - Implementation of the new legislation
- Conclusion



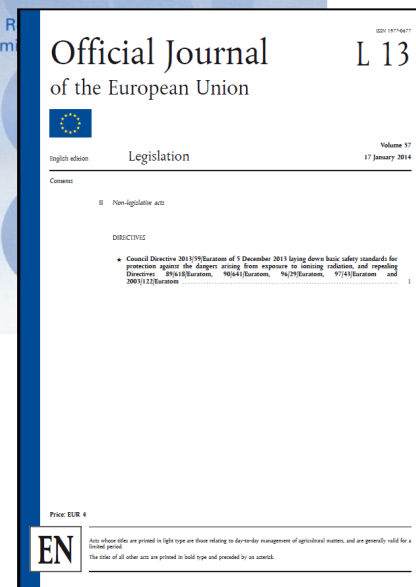
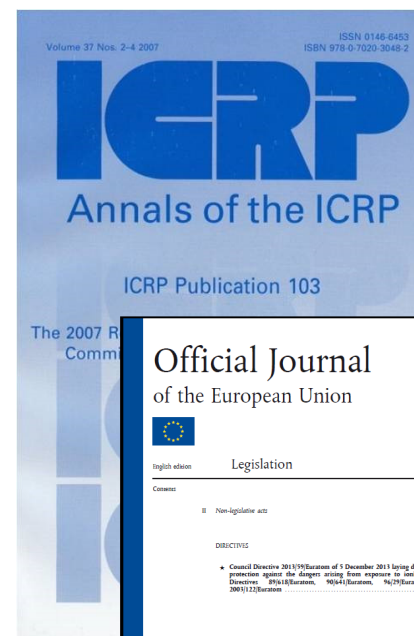
Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate
Radiation Protection Division

Revision of the radiation protection legislation

Objectives

- Transposition of ICRP 103
- **Compatibility with Eu / IAEA BSS**
- In accordance with Swiss law
- Keep it simple and pragmatic
- Graded approach





Swiss legislation

- The Swiss legislation on radiation protection is in force since 1994. It is based on the recommendations of ICRP of 1990 (ICRP 60).
- The recommendations of ICRP 103 (2007) is now implemented into Swiss legislation. An harmonization to the radiation protection concepts of the EU was achieved.
- Euratom Basic Safety Standards Directive (Draft and final version) but also IAEA BSS served as a guideline for the revision of the Swiss radiation protection legislation.



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate
Radiation Protection Division

Revision of the radiation protection legislation

Scope

- Radiation Protection Ordinance
- 10 technical ordinances
(500 pages, more 1500 articles)
- Lead by FOPH

Timeline of the project

2011-2014
Redaction

Autumn 2014
1st
Consultation
(federal offices)

Summer 2015
Public
Consultation
(Stakeholders)

2016
2nd
Consultation
(federal offices)

2017 April
Accepted by
Federal
Council

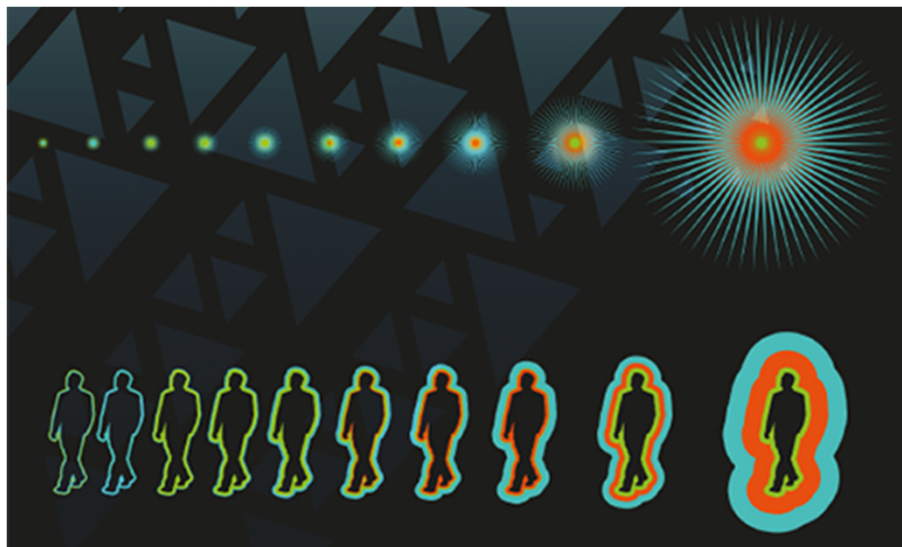
2018 January
Revised
legislation into
force





Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate
Radiation Protection Division



www.strahlenschutzrecht.ch
www.legislationradioprotection.ch
www.dirittoradioprotezione.ch

Press release with flyers

Approved by the Federal Council: 26 April 2017

Entry into force: 1 January 2018



Main changes

Protection Patients

- Implementation of 3 levels of justification (referral guidelines) Art. 27 -30
- Introduction of clinical audits Art. 41 - 43
- Clarification involvement of medical physicists Art. 36
- Adaptation of Concept of optimisation (units, software...) Art. 32, 35

Protection Public and Environment

- New clearance levels (EU-BSS & different scenarios) Annexe 3
- New release criteria for therapy patients in nuclear medicine Art. URAM Ord.
- New immission limits (air, water) → 0.3 mSv/year Art. 24, An. 7
- Dose limits for eye lens and skin Art. 58, 202
- Security and safety of radioactive sources (HASS, orphans) Art. 96 -100

Protection Workers

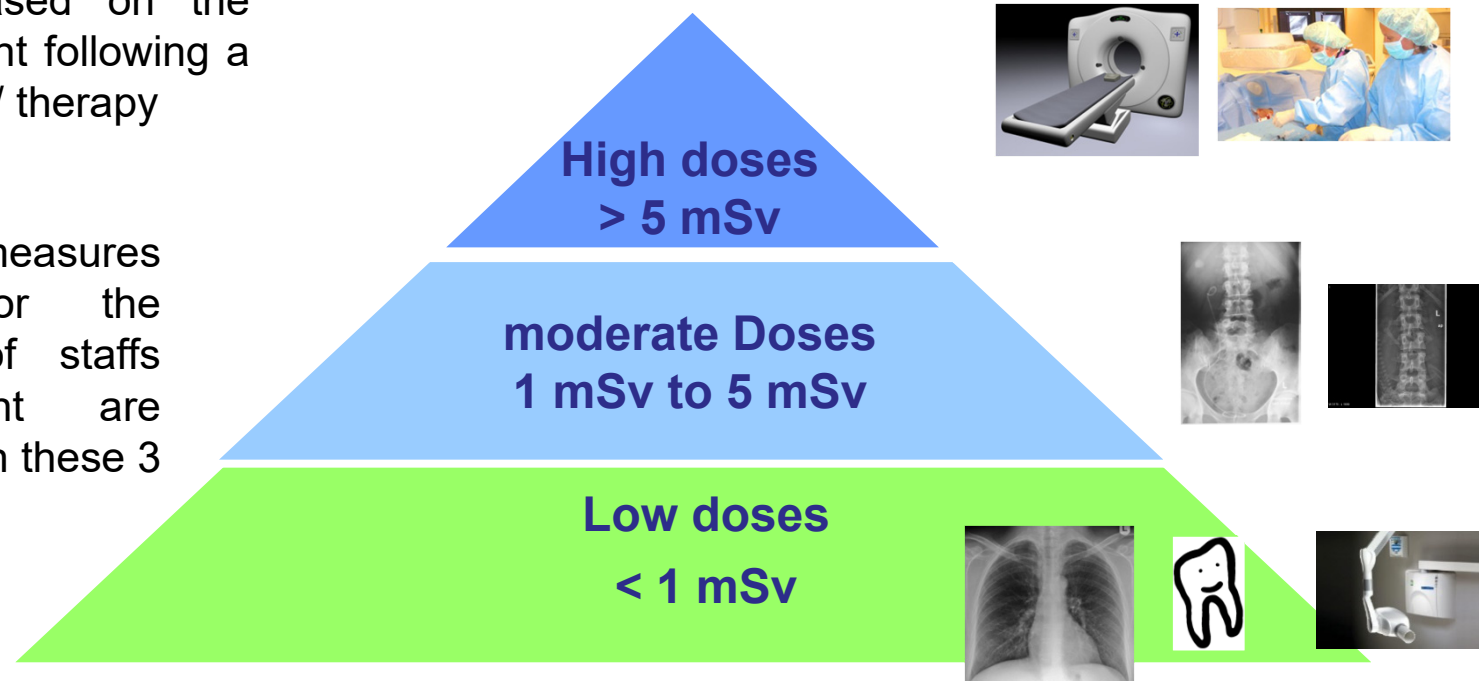
- Lowered dose limit for the eye lens Art. 56
- New factor for the calculation of extremity dosimetry Art. 13 Dos. Ord.
- Mandatory continuous education Art. 175
- Introduction of category A and B Worker Art. 52



Graded approach in the medical field

3 domains for the dose in medicine based on the risk for patient following a examination / therapy

Rules and measures required for the protection of staffs and patient are depending on these 3 domains.

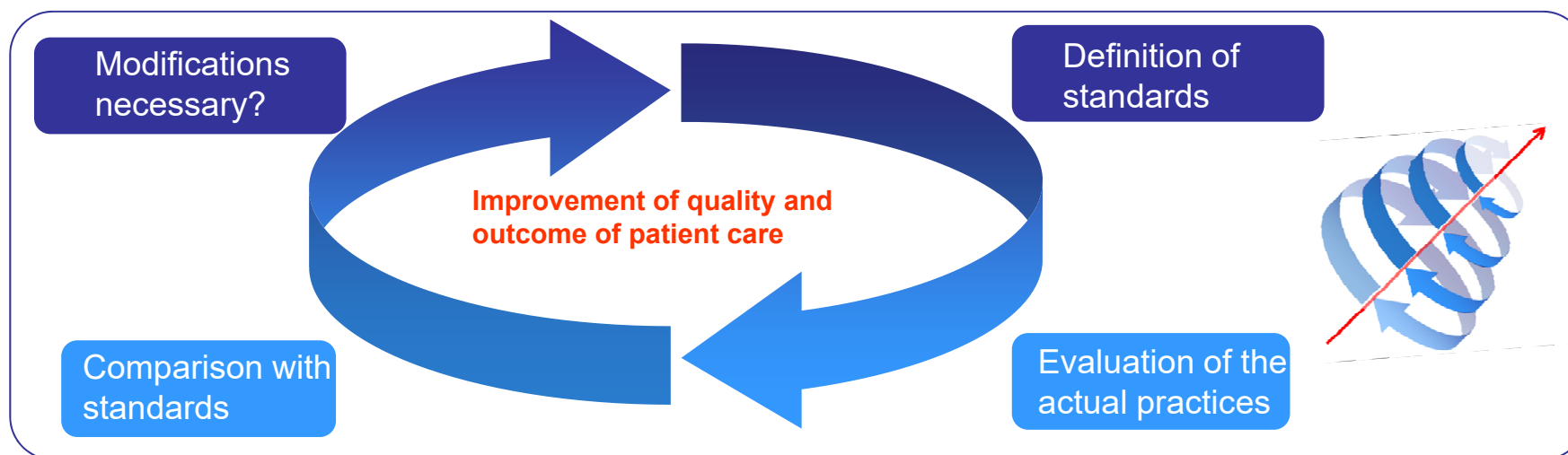




Introduction of Clinical audit

«Systematic examination or review of medical radiological procedures, which seeks to improve the quality and the outcome of patient care, against agreed standards (...)»

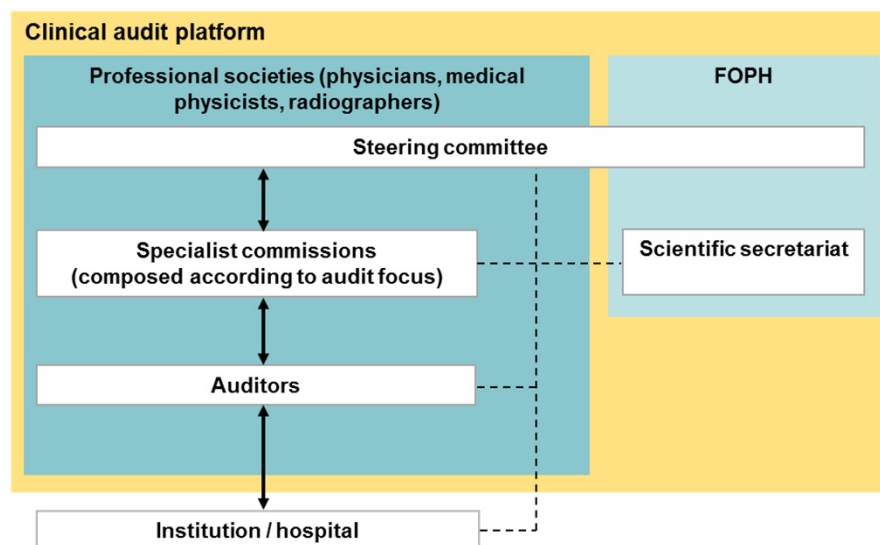
2013/59/EURATOM



- Neither control nor inspection of a regulatory body
- **Peer-review** system



Introduction of Clinical Audits



Art. 41-43:

- quality manual and yearly self evaluation
- voluntary audits during the transition period of 2 years
- soon: Publication of fact sheet
- September 2017: Information letter to hospital/institute management
- February 2018: Detailed information for license holders

www.clinicalaudits.ch



Dose constraint in medicine

- **No limits** for patients (no change)
- Diagnostic Reference Level (DRL) for patients (no change)
- New dose constraint for Carers and comforters: **5 mSv/y**
- Dose constraint for Volunteers in biomedical research:
5 mSv/y up to 20 mSv/y



Criteria, liberation of patient, I-131, etc.

- Criteria for release of patient after therapy

present ordinance	New ordinance
5 μ Sv/h @ 1 m from patient	10 μ Sv/h @ 1 m from patient

Consequence:

Patient can be released earlier

Radioprotection measures taken from the patient to protect their family (restriction of close contact to child, pregnant women etc.) has to be followed during longer period.

- Ambulant therapy possible for patient

present ordinance	New ordinance
200 MBq Possible up to 400 MBq (med. or social reasons)	200 MBq Possible up to 400 MBq (med. or social reasons)



Quality assurance

- Quality assurance mandatory for the whole chain : from radiology units to the monitor and report
- Use of new directives, recommendations : EU, FOPH, etc.
- New mandatory Licences for firms who install and perform QA also on nuclear medicine units (gamma camera) as well as on monitor units (diagnostic)





Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Education



- Modernisation of the content of the education
- Definition of competences of expert
- Authorised tasks with a given education are precisely defined
- New educations required in radiation protection (dental, Op personal, etc.)
- Introduction of mandatory continuous education (5 years)
- Internal concept
- Responsibility of radiation expert (continuous education)



Occupational exposure

New

- Introduction of category A and B exposed worker
- Flightpersonal: exposed worker up 1 mSv per year, all categorie B
- NORM-Industry: Exposed worker up 1 mSv per year
- Radon exposed worker up 10 mSv per year

New

- Reglementation / Rights for pregnant women
Reglementation for young persons



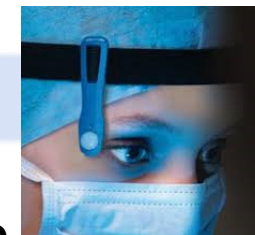
New dose limits

	Public	Occupational
Effective dose	1 mSv / y	20 mSv / y
Lens of the eye	15 mSv / y	20 mSv / y
Skin, extremities	50 mSv / y	500 mSv / y

New limit in 2018



New eye lens dose limits



- International studies show that the eye lens is **more sensitive** to ionizing radiation
- **Decrease of the limit from 150 mSv/y to 20 mSv/y**
- **Introduction of a new quantity in the ordinance** for the dose of the eye lens: $H_p(3)$
- Art. 11 Dosimetry Ordinance define the way to **measure the dose to the eye with conventional** body dosimeter:

$$H_{\text{eye lens}} = f_L * H_p(0.07)$$

- $H_{\text{eye lens}} = H_{\text{under}}(0.07) + f_L * H_{\text{above}}(0.07)$ (interv. Radiology)

with f_L = correction factor for lead glasses or
other protection measures

etc.



Dosimetry



- **New mandatory of double dosimetry** (whole body) for interventional radiologist and high dose work
- **Extremity dosimetry**: If an activity of more than **200 LA (LA activity limit for a mandatory licences)** is handled **per year** a need to wear a ring dosimeter is foreseen
- With the revised legislation, extremity dose is newly calculated according to

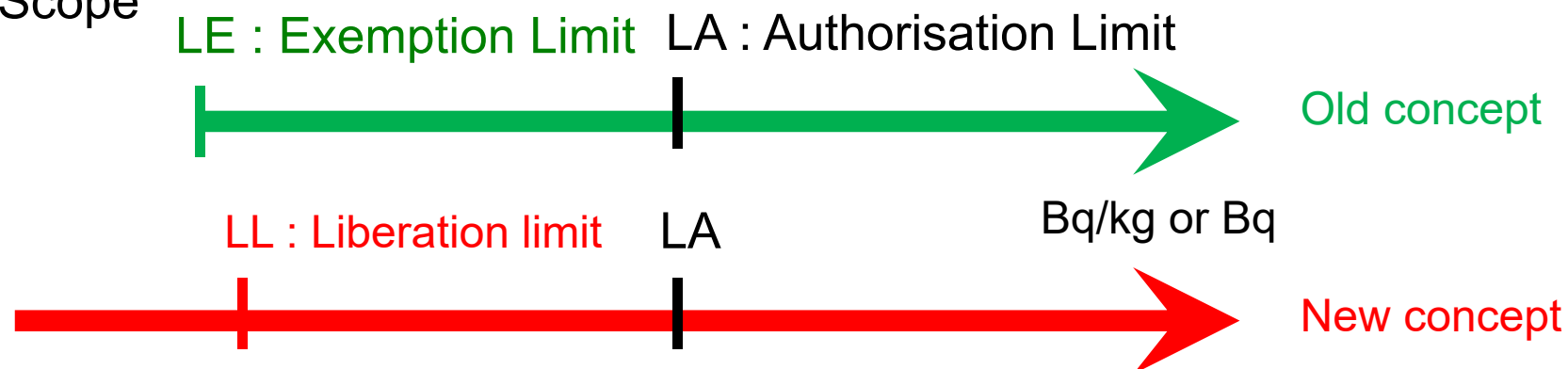
The new Dosimetry ordinance, Article 13

$$H_{\text{extr}} = f_E * H_p(0.07)$$

with a standard correction factor of **$f_E = 5$**

New concept for the scope / exemption / liberation

Scope



- Old: radioactive substance: no more radioactive when under limit (LE)
- New: everything is radioactive but not subject to authority control if under a specific activity or activity LL, no under limit to the scope
- Liberation / Clearance level LL – like Euratom BSS
- Authorisation limit LA / licence up a given activity – keep Swiss value



Clearance / Liberation Limit (LL)

- These values are in the BSS only available for less than 300 radionuclides, whereas we need a complete set of data for 800 radionuclides in our legislation.
- Therefore we have mandated “*Brenk Systemplanung / Consulting Engineers / Germany*” to do the necessary calculations for the 500 missing radionuclides.



New LL value for Liberation/clearance

Old concept

LE: Exemption Limit : Bq or Bq/kg

Activity not in the scope

New concept

LL: Liberation Limit : Bq/g

Activity to exit the system

New hypotheses

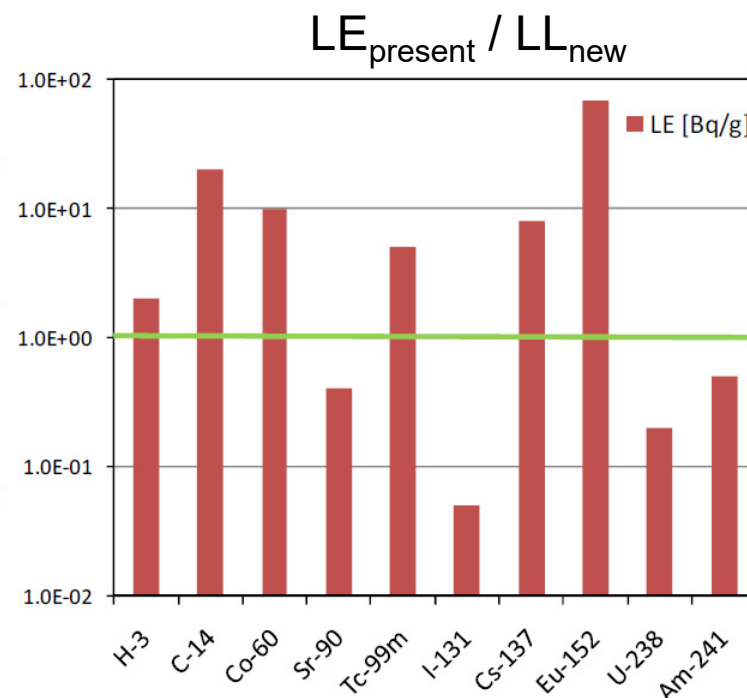
(not ingestion but contaminated landfill, etc)

Nuclear power plant (NPP):

Waste amount (volume) from decommissioning of NPP will increase by 25%.

Medicine, industry, research:

Small impact, except decommissioning of research accelerators / accelerators used for production of radiopharmaceuticals (Co-60)





Annex III, Radiation Protection Ordinance (LL)

Verordnung

814.501

Nuclide		e inh		LL		LA		CS					
Radionuklid	Halbwertszeit	Zerfallsart/ Strahlung	Richtwerte										
			e_{inh} Sv/Bq	e_{ing} Sv/Bq	$h_{0,01}$ (mSv/h)/ GBq in 1 min Abstand	$h_{0,07}$ (mSv/h)/GBq in 10 Abstand	$h_{0,07}$ (mSv/h)/ cm(kBq/cm ²)	LL Bq/g	LA Bq	CA Bq/m ³	CS Bq/cm ²	Instabiles Tochternuklid	
	2	3	4	5	6	7	8	9	10	11	12	13	
Fr-222	14.2 m	β ⁻ / ph	2.10E-08	7.10E-10	0.001	1000		1.6	1.E+03 [2]	3.00E+03	4.00E+02	3	→ Ra-222 etc.
Fr-223	22.00 m	β ⁻ , α / ph	1.30E-09	2.30E-09	0.017	2000		1.8	1.E+03 [1]	5.00E+06	6.00E+03	3	→ Ra-223
Ra-223	11.43 j	α / ph	5.70E-06	1.00E-07	0.024	600		0.5	1.E+01 [2]	1.00E+03	1.00E+00	3	→ Rn-219 → Po-215 → Pb-211
Ra-224	3.66 j	α / ph	2.40E-06	6.50E-08	0.002	30		<0.1	1.E+00 [2]	3.00E+03	3.00E+00	3	→ Rn-220 etc.
Ra-225	14.9 j	β ⁻ / ph	4.80E-06	9.50E-08	0.007	1000		0.9	1.E+01	1.00E+03	2.00E+00	3	→ Ac-225
Ra-226	1600 a	α / ph	2.20E-06	2.80E-07	0.001	50		<0.1	1.E-02 [2]	3.00E+03	4.00E+00	1	→ Rn-222
Ra-226 (+ filles)					0.283	5000		5.2	1.E-02	xxxx	xxxx	1	
Ra-227	42.2 m	β ⁻ / ph	2.10E-10	8.40E-11	0.038	2000		1.8	1.E+02 [1]	3.00E+07	4.00E+04	3	→ Ac-227
Ra-228	5.75 a	β ⁻ / ph	1.70E-06	6.70E-07	<0.001	<1		<0.1	1.E-01 [2]	4.00E+03	5.00E+00	0.3	→ Ac-228
Ac-224	2.78 h	ec, α / ph	9.90E-08	7.00E-10	0.038	100		0.2	1.E+02 [1]	6.00E+04	8.00E+01	30	→ Ra-224, Fr-220 etc.
Ac-225	10.0 j	α / ph	6.50E-06	2.40E-08	0.005	20		0.1	1.E+01 [2]	9.00E+02	1.00E+00	10	→ Fr-221 etc.
Ac-226	29.37 h	β ⁻ , ec, α / ph	1.00E-06	1.00E-08	0.024	1000		1.3	1.E+02 [2]	6.00E+03	8.00E+00	3	→ Th-226, Ra-226, Fr-222
Ac-227	21.772 a	β ⁻ , α / ph	6.30E-04	1.10E-06	<0.001	<1		<0.1	1.E-02 [2]	1.00E+01	1.00E-02	0.1	→ Th-227, Fr-223
Ac-228	6.15 h	β ⁻ / ph	2.90E-08	4.30E-10	0.145	2000		1.8	1.E+01 [1]	2.00E+05	3.00E+02	3	→ Th-228
Th-226	30.57 m	α / ph	7.80E-08	3.60E-10	0.002	100		0.3	1.E+03 [1]	8.00E+04	1.00E+02	30	→ Ra-222 etc.
Th-227	18.68 j	α / ph	7.60E-06	8.90E-09	0.023	200		0.2	1.E+01	8.00E+02	1.00E+00	10	→ Ra-223
Th-228	1.9116 a	α / ph	3.20E-05	7.00E-08	0.002	3		<0.1	1.E-01 [2]	2.00E+02	3.00E-01	3	→ Ra-224
Th-229	7.34 E3 a	α / ph	6.90E-05	4.80E-07	0.027	300		0.5	1.E-01 [2]	9.00E+01	1.00E-01	0.3	→ Ra-225
Th-230	7.538 E4 a	α / ph	2.80E-05	2.10E-07	0.001	3		<0.1	1.E-01	2.00E+02	3.00E-01	1	→ Ra-226
Th-231	25.52 h	β ⁻ / ph	4.00E-10	3.40E-10	0.018	700		0.8	1.E+03	2.00E+07	2.00E+04	10	→ Pa-231
Th-232	1.405 E10 a	α / ph	2.90E-05	2.20E-07	0.001	3		<0.1	1.E-01 [2]	2.00E+02	3.00E-01	1	→ Ra-228
Th-234 / Pa-234m	24.10 j	β ⁻ / ph	5.80E-09	3.40E-09	0.008	1000		1.9	1.E+02 [2]	1.00E+06	1.00E+03	3	→ Pa-234
Th nat (+ filles)					0.355	6000		5.4	siehe Anhang 4			1	
Pa-227	38.3 m	α, ec / ph	9.70E-08	4.50E-10	0.007	5		<0.1	1.E+01 [1]	6.00E+04	9.00E+01	300	→ Ac-223
Pa-228	22 h	ec, β ⁻ , α / ph	5.10E-08	7.80E-10	0.168	400		0.9	1.E+01	1.00E+05	2.00E+02	10	→ Th-228, Ac-224
Pa-230	17.4 j	ec, β ⁻ , α / ph	5.70E-07	9.20E-10	0.108	200		0.3	1.E+01	1.00E+04	1.00E+01	30	→ Th-230, U-230, Ac-226
Pa-231	3.276 E4 a	α / ph	8.90E-05	7.10E-07	0.020	40		0.1	1.E-01	7.00E+01	9.00E-02	0.3	→ Ac-227



Environmental and population protection

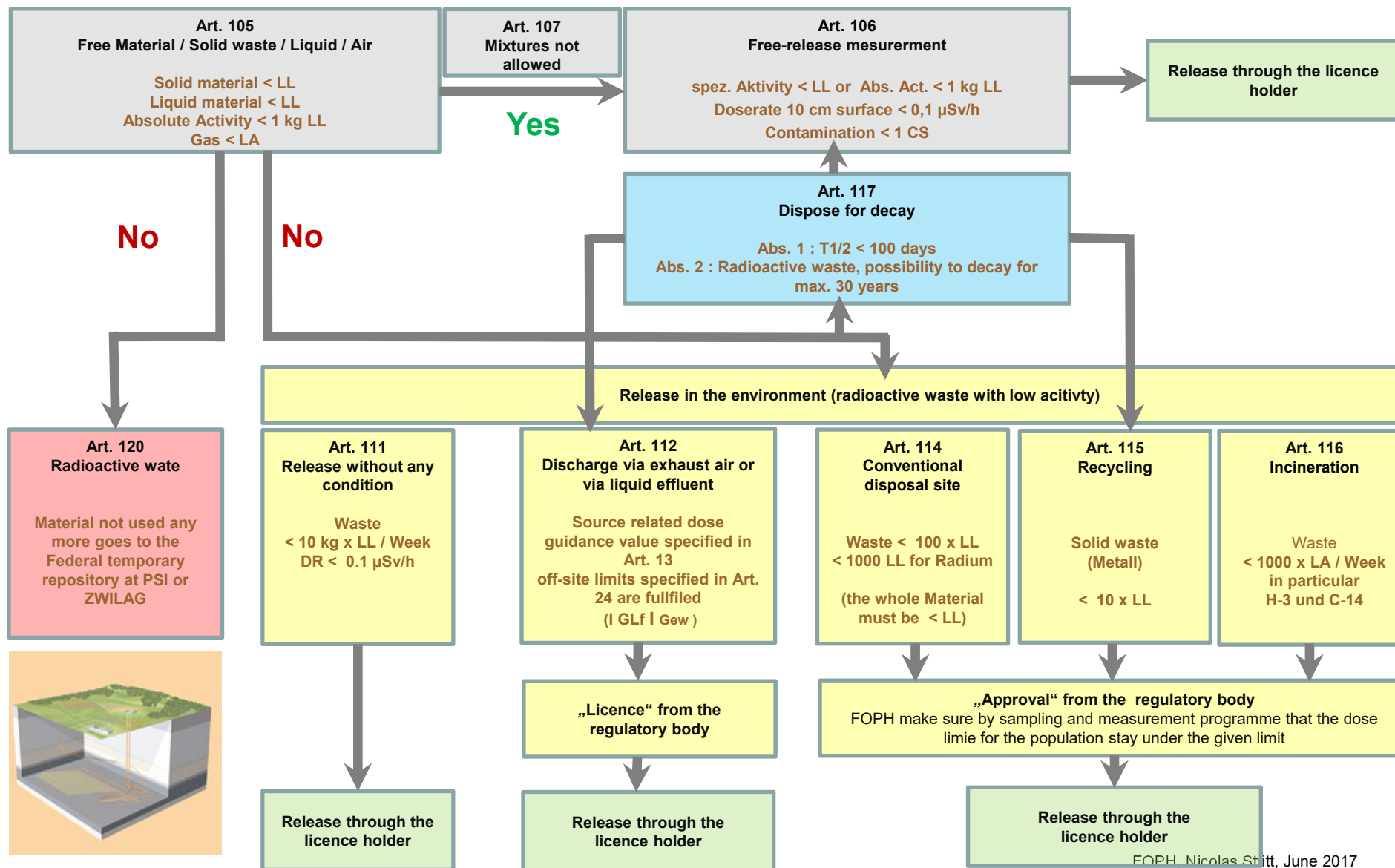
- Immission limit for effluent air and water
 - Air: 0.3 mSv / y through inhalation und immersion
 - Water: consummation of 650 l /year give rise to a dose of 0.3 mSv
- Replacement of tolerance value for food
- No other protection of the environment (animal, etc.)



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

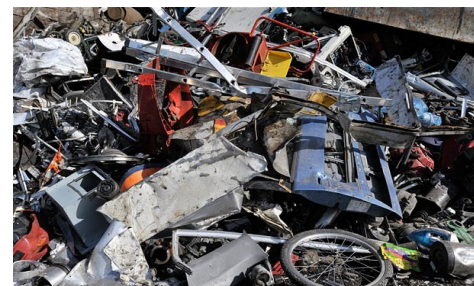
LL : Freigrenze
LA : Bewilligungsgrenze
CS : Oberfläche Kontamination
I_{GLF} : Immissionsgrenzwerte für Gewässer
I_{Gew} : Immissionsgrenzwerte für Gewässer

Radioactive material discharge



Re-enforcement of measurement of radioactivity

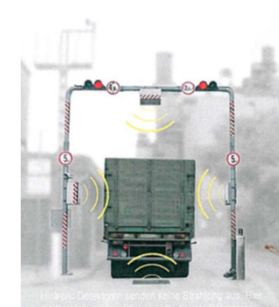
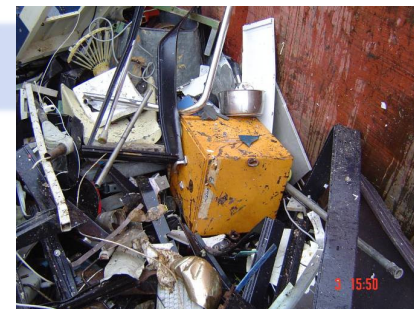
- To protect the workers, the population and the environment
- To avoid illegal discharged in the environment
- To avoid that radioactive material enter or exit the country unattended
- Metal scrap dealers and other industries like incineration centres, etc. are required to measure their material for the presence of radioactivity
- As they may encounter radioactivity a licence for the measurement as well as for the disposal and manipulation of radioactive material will be required





Radioactivity at the Swiss border

- Introduction in the legislation of a concept to measure radioactivity at the border
- Collaboration between SFOPH Office of Border Gards office
- Control of radioactivity by import and export
- Measurement at the border is now on going with different mobile measurement systems





Authorisation

- Licence
- Simplify licence (mainly dentist, small RX Services)
- Specifically exempt („New type of licences“)

According to the radioprotection law, the use of ionizing radiation to human is subject to authorisation, this stay the same (no change in the law)

New licences

- NORM-Industrie:
 - from 1.0 mSv for workplace
 - from 0.3 mSv in the environment
 - Radon workplace
- Manipulation or in contact with orphan sources



Building material

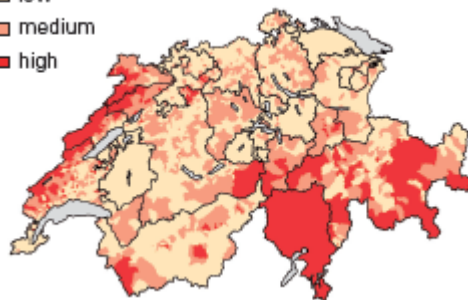
- **Use of the activity concentration index (I) for the gamma radiation emitted by building materials according to Euratom BSS**
 - Building material with $I < 1$
No restrictions on the envisaged use of such materials
 - Building material with $I > 1$
should not give doses exceeding 1 mSv / y



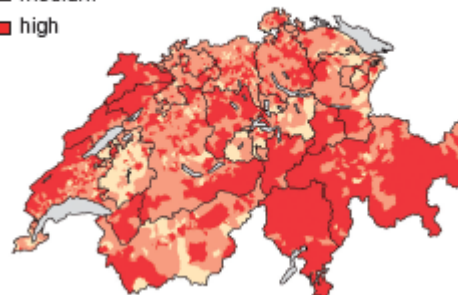
Buildings concerned

Home and dwellings with concentration higher than the limits of	1000 Bq/m ³	300 Bq/m ³
Already identified	3000 building (2%)	15'000 building (12%)
Estimation for all Switzerland	5000 - 10'000 building	50'000 - 100'000 building

low
medium
high



low
medium
high



Graded approach for radon mitigation

- Radon mitigation, in case of exceeding 300 Bq/m³ :
- Priority for schools and kindergartens
- Other buildings, dwelling
 - According to emergency of the case und economical criteria
 - Ultimately by the next renovation with building permission
 - Possibility of derogation if the principle of proportionality isn't respected
- Building owner:
 - pays the mitigation costs
 - measures radon after mitigation and inform the authority about result





Radon consultants

- Requirements for the institution organizing radon training, defined in the legislation
- FOPH publishes a list of radon consultants
- Radon consultants on the list are obliged to prove their activity
- Work done according to the state of the art





Workplaces

- Obligation of measurement for the employers in “workplaces with radon risk”: underground facilities, caves and water supplies facilities
- If the integrated radon concentration greater than $1000\text{m}^3/\text{Bq}$ transfer to planned exposure situation





Implementation

- The 11 ordinances will entry into force on the 01.01.2018
- The FOPH directives are actually under revision and will be published before the end of the year
- New limit and LL value will be valid from the 01.01.2018
- Transition period (1-2 years) for different issues (dosimetry, etc.)
- Information will be send after the summer break to inform the licence holder about the main changes
- Some of the licences have to be adapted and will be renewed up the 01.012018



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate
Radiation Protection Division

App developed by regulatory body

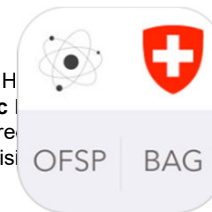
- ❑ The application **NuklidCalc** is a help to get useful values for the radionuclides. This is a compilation of the annexe 3 of the radiation protection ordinance. It offers multiple function useful for radiation protection experts.
- ❑ Applications are free of charge
iphone (available for android soon)





Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs
Federal Office of Public Health
Consumer Protection Division
Radiation Protection Division



App NuklCal, annex 3 of the radiation protection Ord.

The image displays a sequence of overlapping screenshots of the NuklCal app, illustrating its various calculation and data entry screens. The app is designed for radiation protection calculations, featuring multiple input fields, unit selection buttons, and calculation results.

Screen 1 (Leftmost): Shows the main menu with a sidebar containing icons for DONNEES, SECTEURS, NOMBRE D, DEBIT DE, $A_{(t)}$ ACTIVITE A, ACTIVITE (t), CONVERSI, DOSE AUX, and AIDE. The main area displays a list of laboratories: LABO C, LABO B, and LABO A.

Screen 2: Titled "SEC", it shows a calculation for F-18. The main area is mostly obscured by the next screen.

Screen 3: Titled "NO", it shows a calculation for Cs-137, Ba. The main area is mostly obscured by the next screen.

Screen 4: Titled "DEBIT D", it shows a calculation for F-18. The main area is mostly obscured by the next screen.

Screen 5: Titled "AC", it shows a calculation for F-18. The main area is mostly obscured by the next screen.

Screen 6: Titled "ACTIV", it shows a calculation for Co-60. The main area is mostly obscured by the next screen.

Screen 7 (Rightmost): Titled "DOSE AUX EXTREMITES", it shows a calculation for F-18. The main area displays a table of dose rates:

Débit de dose à 1 cm	
70000.0	mSv/h
1166.7	mSv/m

Débit de dose à 10 cm	
700.0	mSv/h
11.667	mSv/m

At the bottom, there is a large display showing "350 MBq" and a unit selection bar with options: Bq, kBq, MBq, GBq, TBq, and PBq.



Conclusion 1

- Revision of 10 Ordinances in radiation protection
- Long project, more than 6 years
- Transposition in accordance with ICRP 103 / IAEA BSS / Eu BSS
- Graded approach according to risk for education, QA, involvement of staff
- Introduction of a continuous education
- New dose limits for the eyes lens (20 mSv/year)
- Introduction of a correction factor for extremity dosis



Conclusion 2

- More focus on justification principle in medicine
- Introduction of new type of audit, clinical audit
- New clearance level (radioactive waste, LL value)
- New limit for release of radioactive liquid
- New limit for the liberation of patient after iodine therapy
- New limit for Radon / NORM
- New License Mandatory for work with Radon / NORM



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate
Radiation Protection Division

Thank you for your attention



Bern, Switzerland