



How does Greece plan to implement the new BSS in its regulatory context when it comes to the graded approach?

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Introduction



- The implementation of a graded approach in the regulatory context is considered a challenge; As the risk associated with a practice increases the regulatory process should become more stringent (effectively);
- In February 2018 the transposition of the new EU BSS in the national legislation has to be completed;
- A working group has been formed within EEAE, assigned with the preparation of the required legislative documents. The group consists of special scientific personnel from EEAE:
 - Licensing & inspections;
 - Environmental radioactivity;
 - Personal dosimetry service;
 - Emergency response;
 - Education & Training;
 - Office of legal affairs;
- Contacts with other scientific professions/societies and stakeholders.

EU Directive 2013/59

Recitals:

- (36) Member States should benefit from the application of a **graded approach** to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from the practices, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.



EU Directive 2013/59

Article 24

Graded approach to regulatory control

1. *Member States shall require practices to be subject to regulatory control for the purpose of radiation protection, by way of notification, authorisation and appropriate inspections, commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving radiological safety.*



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2. Without prejudice to Articles 27 and 28, where appropriate, and in accordance with the general exemption criteria set out in Annex VII, **regulatory control may be limited to notification and an appropriate frequency of inspections.** For this purpose, Member States may establish general exemptions or allow the competent authority to decide to exempt notified practices from the requirement of authorisation on the basis of the general criteria specified in Annex VII; in the case of moderate amounts of material, as specified by Member States, the activity concentration values laid down in Annex VII, Table B, column 2 may be used for this purpose.

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3. Notified practices which are not exempted from authorisation shall be subject to regulatory control through registration or licensing.

Number of radiation facilities (2015)

A/a	Category	Number
1	Radiology	1178
2	Nuclear Medicine	178
3	Teletherapy (linear accelerators)	24
4	Teletherapy (60Co)	7
5	Brachytherapy	17
6	Radiotherapy X-ray	1
7	Research	200
8	Industrial units with radiation systems and sources	324
9	Blood irradiators	14

Number of radiation facilities (2015)

A/a	Category	Number
10	Isotopes production unit	1
11	Sterilization unit	1
12	Veterinary laboratories with x-ray systems	234
13	Dental laboratories with x-ray systems	7226
Special facilities		
14	Research Nuclear Reactor	1
15	Tandem Accelerator	1
16	Interim storage of radioactive sources and waste facility	1

Number of systems per category - Radiotherapy

A/a	Type	#
1	Linear accelerators	39
2	Teletherapy ^{60}Co	6
3	Stereotactic systems	3
4	Brachytherapy ^{125}I - ^{106}Ru	6
5	Brachytherapy ^{192}Ir	9
6	Brachytherapy ^{137}Cs	1
7	Computer tomography simulators	16
8	Classic simulators	13

Number of systems per category - Radiology

A/a	Type	#
1	Radiography units	915
2	Radiology units	419
3	Fluoroscopy units	26
4	Dig. angiography systems	68
5	Coronary angiography units	50
6	Computer tomography units	384
7	Mammography units	644
8	Mobile radiographic units	473
9	Mobile fluoroscopic units	286
10	Bone densitometer units	601
11	Conventional dental radiography systems	7226
12	Panoramic	553
13	Dental Computed Tomography	20

Number of systems per category – Nuclear Medicine

A/a	Type	#
1	PET/CT	5
2	γ -camera systems	156
3	Scintigraphy units	2
4	β counters	6
5	γ counters	162

Number of systems per category

A/a	Type	#
Industrial applications		
1	Sources	727
2	Radiography	36
3	Soil texture systems	101
4	XRF & X-ray	132
Research		
1	Counters (β & γ), XRF, Xray, etc.	105
2	Radioactive sources	1175

Number of systems per category – Other applications

A/a	Type	#
1	Veterinary X-ray	234
2	Blood irradiators	14
3	Sterilization unit	1
4	Isotope production unit	1

Stakeholders

The list of stakeholders and individuals, which EEAE activities relate to, includes:

- Workers occupationally exposed to radiation - more than 11,000 workers in our country;
- Persons medically exposed to radiation (diagnosis, treatment);
- More than 100 enterprises and companies in the industry,
- Trade and services;
- Local authorities;
- Education and training institutions;
- Authorities involved in the protection of the environment,
- Public health and in civil protection plans;
- Embassies and permanent representations to international organizations.



Current authorisation procedure (licensing)

According to the current authorisation procedure:

- All ionising radiation facilities must be **licensed** (no registration);
- The license is valid for 3 or 5 years (depending on the type of the facility). After this period a renewal is required;
- Inspections are part of the licensing procedure;
- No notification, but a feasibility license (justification);



EEAE role

- Law 4310 (Government Gazette Folio No. 258/A/08.12.2014) titled “Research, Technological Development and Innovation and other provisions”:
 - EEAE is explicitly designated as Regulatory Authority for the control, the regulation and the supervision of the sector of nuclear energy, nuclear technology, radiological and nuclear safety and radiation protection;
 - EEAE acquires complete administrative and financial independence, keeps its scientific character and is given the form of public entity;
 - **EEAE as regulatory authority is henceforth the licensing administrative authority;**
 - inspection procedures and inspectors role are reinforced significantly;
 - Law enforcement means are provided, by specifying administrative and penal sanctions;
 - EEAE is provided with the power to conduct hearings and public consultations, and to issue a number of regulations.



Legislative framework

Presidential
Decree

Ministerial Decision

Regulatory acts

Guidelines, other
supportive
documents

- Regulatory acts, guidelines and supportive documents could be easily amended in order their provisions to reflect the continuous developments in technology, radiation protection and scientific evidence.



Under consideration...



- For the implementation of graded approach the following parameters are considered:

The type of practices – associated risk

Safety & Security (separately assessed BUT integrated in authorization)

The history of the facilities in respect to radiation protection

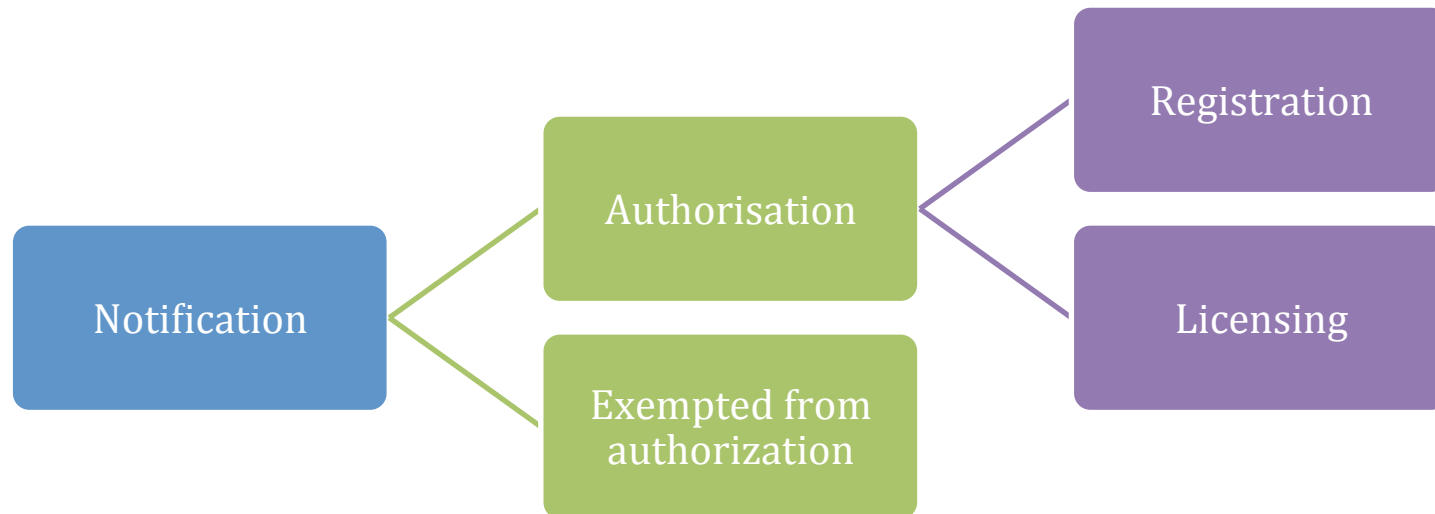
Incidents, events, near misses (actual & potential)

Data from National Radiation Protection Data Base (NRPD) regarding occupational exposures - overexposures

The experience from the on-site inspections of EEAE's personnel

Other parameters

Authorisation of practices

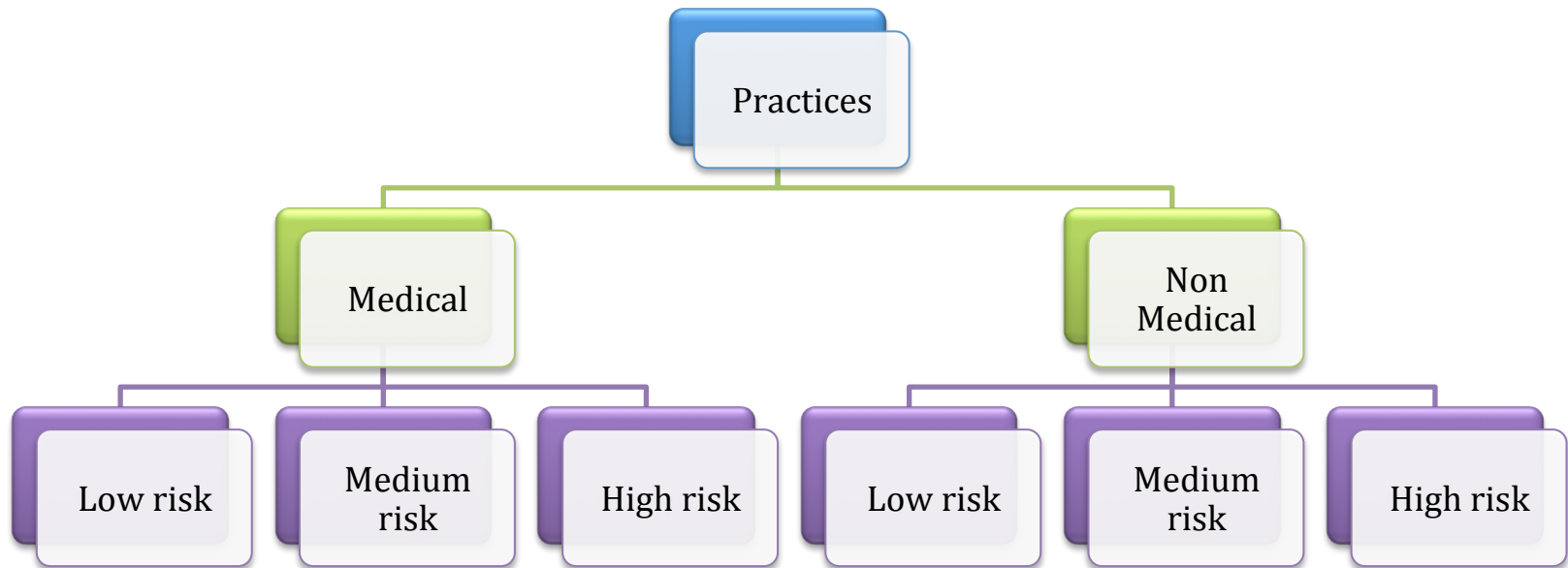


Exemption

AUTHORISED

Categorization of practices

The categorization of practices after the implementation of the graded approach could be reflected in the following scheme:



Notification

- Submission of information by the interested person/company in order to notify EEAE for the intention to carry out a practice within the scope of the Ministerial Decision (also for exempted practices and authorization). More specifically:
 - a. EEAE issues a regulatory act which defines the practices exempted from authorization which need notification. For these practices, EEAE issues only a “notification” document.
 - b. For the practices to be authorised (registered, licensed), notification will be incorporated in the registration/licensing procedure.



Medical practices



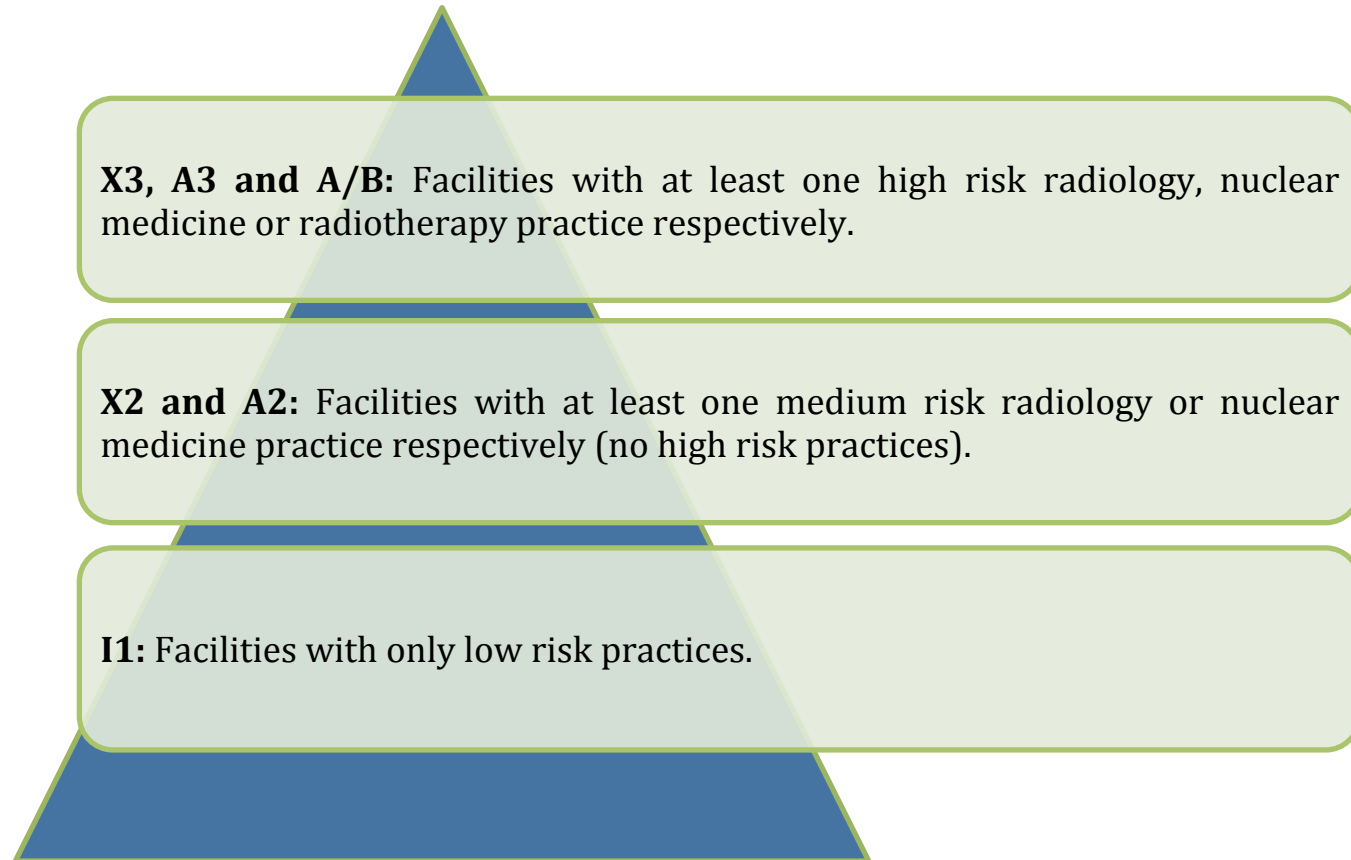
Medical-High risk: Fluoroscopically guided interventional procedures, CT cardiology procedures, CT fluoroscopy, PET-CT, radiotherapy, brachytherapy, radioisotope therapies.

Medical-Medium risk: Radiography or/and fluoroscopy, CT, mammography, panoramic examinations, CBCT, nuclear medicine in vivo examination.

Medical -Low risk: Dental radiography, DEXA.

- Practices not included in the above categories could be classified ad-hoc by EEAE.

Categorization of medical undertakings /facilities



Authorisation of medical undertakings/facilities

X3, A3 and A/B:

Licensing

- The employment of a RPO and a RPE **and** MPE should be a requirement.

X2 and A2:

Licensing

- The employment of a RPO should be a requirement.

I1:

Registration



Non Medical practices - Veterinary

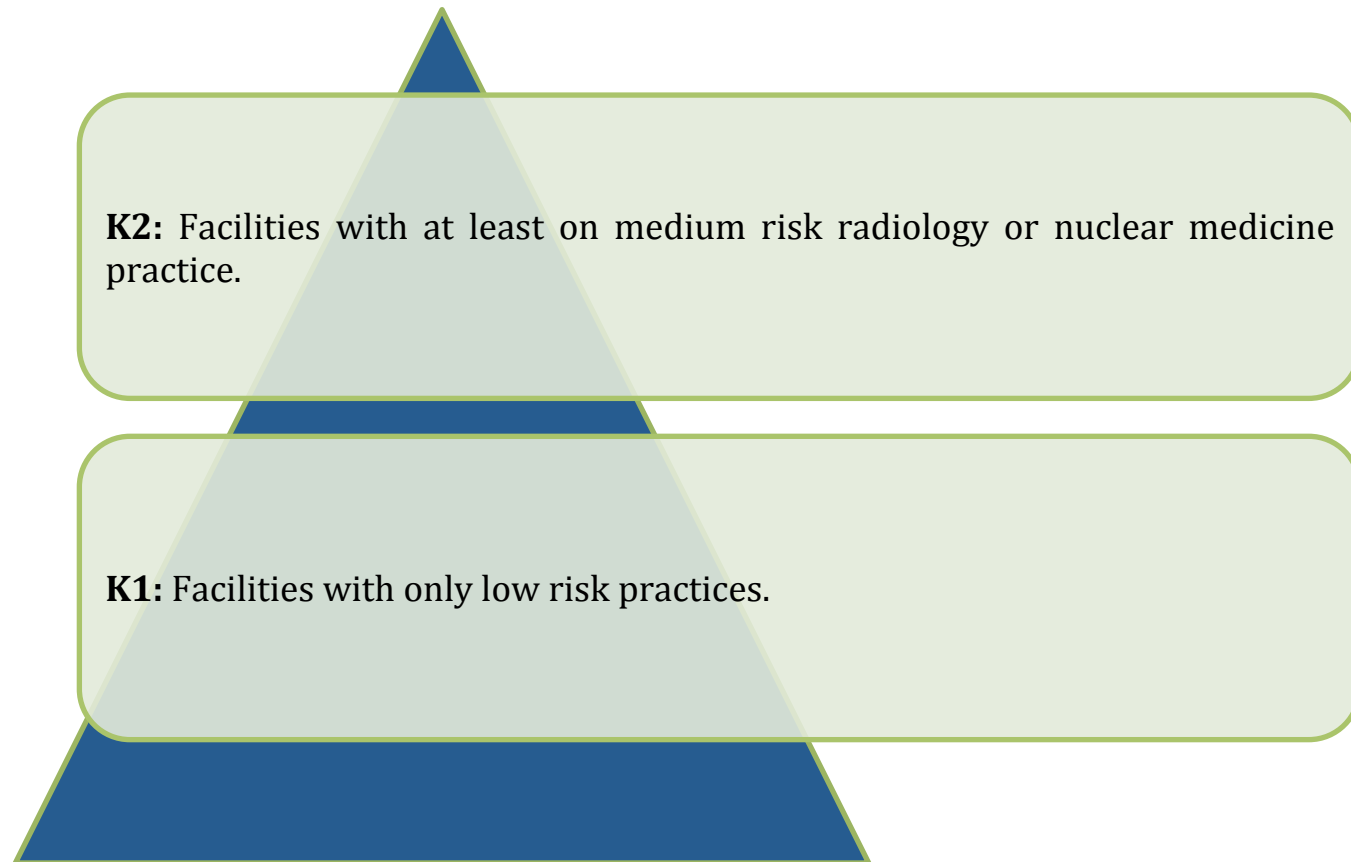


Veterinary-Medium risk: CT, nuclear medicine, radiotherapy

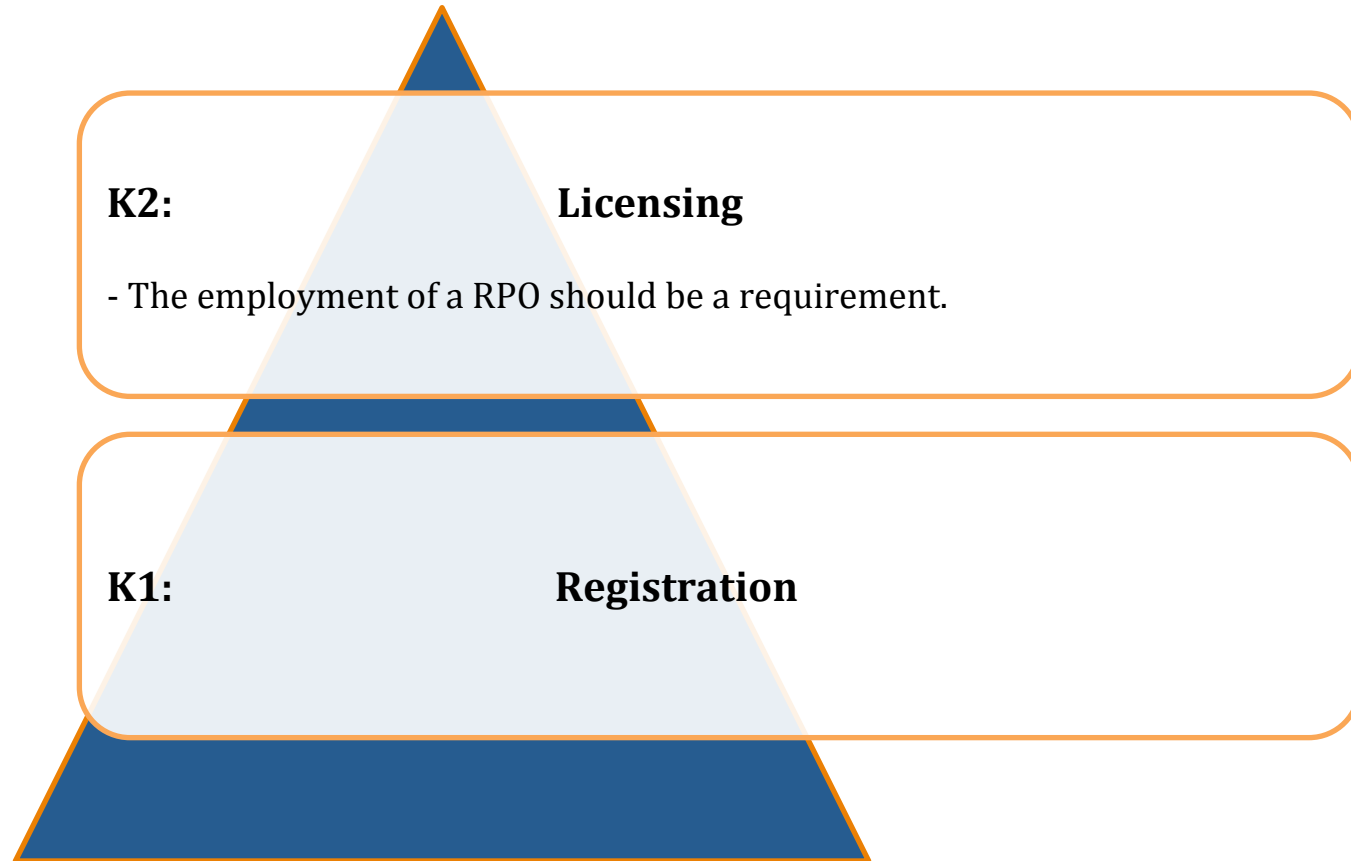
Veterinary -Low risk: Radiography

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Categorisation of veterinary undertakings/facilities



Authorisation of veterinary undertakings/facilities



Non medical practices



High risk: Use of

- category 1 and 2 radioactive (sealed) sources (irradiators, industrial radiography sources, etc.) or/and
- industrial radiography x-ray systems or/and
- electron or particle accelerators of > 500 kV or/and
- isotope production systems.

Medium risk: Use of

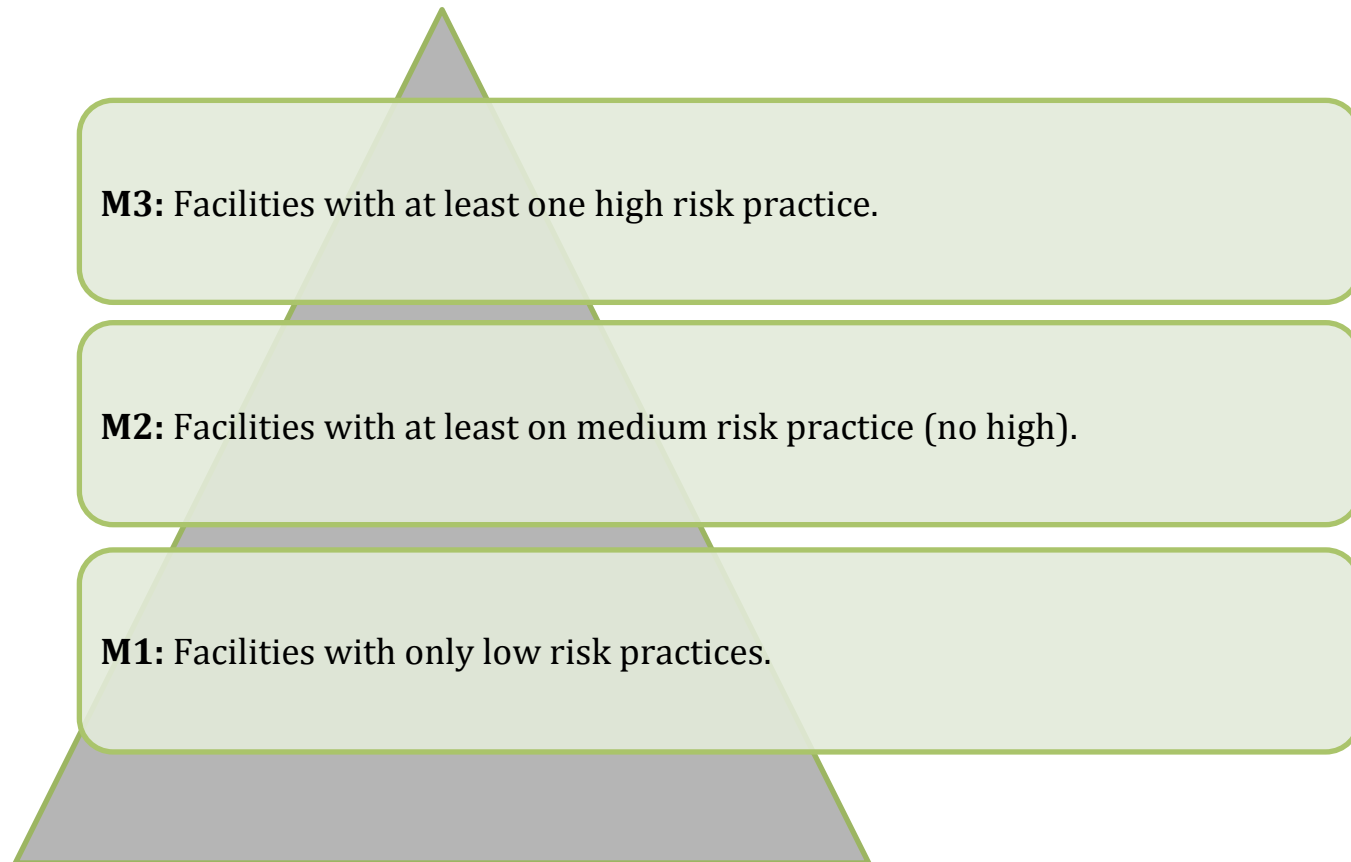
- category 3 and 4 radioactive (sealed) sources or/and
- unsealed sources of activity per use/experiment over 1000 times the exemption level.

Low risk: Use of

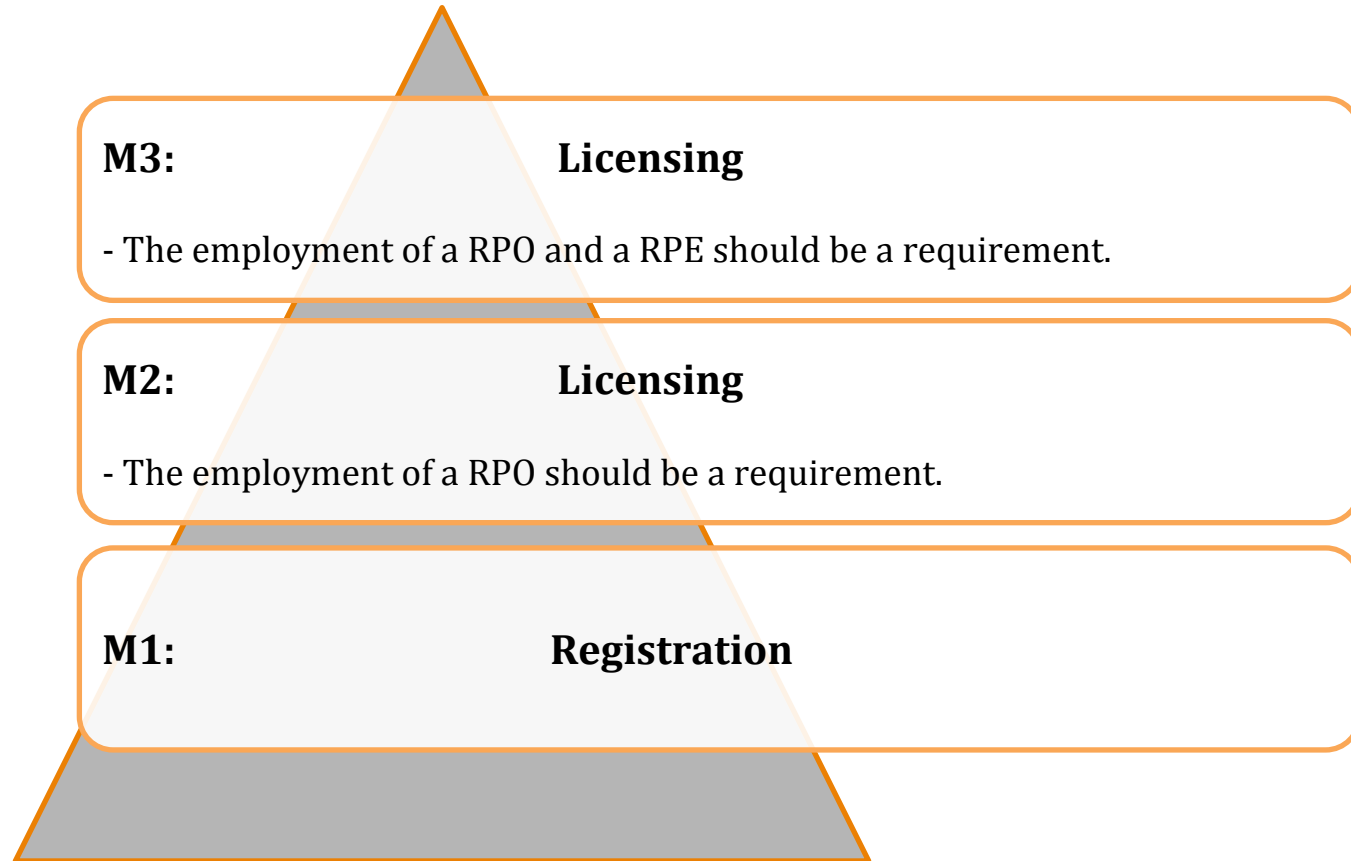
- category 5 radioactive (sealed) sources, sources or/and
- unsealed sources of activity up to 1000 times the exemption level or/and
- radioactive materials of activity up to 1000 times the exemption level, etc.

- Practices not included in the above categories could be classified ad-hoc by EEAE.

Categorisation of non medical undertakings/facilities



Authorisation of non medical undertakings/facilities



Authorisation validity period

- Max. 5 years for licensed facilities, but may be lower depending on inspection findings, the history of the facility, etc;
- Under consideration :
 - High risk practices - max 3y,
 - Medium risk practices - max 5 y,
 - Low risk practices (registration) - ∞



Inspections

A/a	Public sector	Private sector	Total
Radiotherapy	8	7	15
Radiology	143	239	382
Nuclear Medicine	17	45	62
Dental	1	26	27
Research	51	-	51
Industrial applications	16	44	60
Veterinary radiography	1	19	20
Blood irradiators	2	5	7
Other		3	3
Total	239	388	627



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Inspections

- Not connected to the licensing procedure;
- Establishment of a Biannual Inspection Program:
 - some high risk practices;
 - previous inspection results, facility history;
- Frequency (???):
 - R/T every 1,5 year;
 - High risk practices: every 2 years;
 - Medium risk practices: every 3-4 years;
- Inspection content & depth based on graded approach – Defined prior inspection;
- Areas covered during inspection: Security/Personnel/Procedures/QA-QC, etc;



Review & Assessment

- Special attention will be paid to the review and assessment of documentation submitted during the authorisation procedure;
- The requirements concerning the submitted documentation would commensurate with the risk associated to practices;
- The information of the reports submitted to EEAE for evaluation should also follow the graded approach (risk category).



Challenges

- To define the role and the responsibilities of the RPOs, RPEs, MPs and MPEs.
- How to establish an authorisation system:
 - Realistic (neither underestimate nor overestimate risk);
 - Sustainable;
 - Effective;
 - Taking advantage of the available human resources & infrastructure;
 - Adaptable to country needs & conditions;
 - Not bureaucratic.



Thank you!!!

