EEAE ΕΛΛΗΝΙΚΗ ΕΠΙΤΡΟΠΗ ΑΤΟΜΙΚΗΣ ΕΝΕΡΓΕΙΑΣ
GREEK ATOMIC ENERGY COMMISSION

Sharing experience: Application of Graded Approach in Authorization

Dr Eleftheria Carinou
Deputy Director
Licensing and Inspections Division

Webinar: *Application of a Graded Approach in Regulating the Safety of Radiation Sources Tuesday, 8 December 2020*

General outline of the presentation

- Why Graded Approach?
- How to set the methodology?
- Application of GA
- Current status and Future actions

Why do we need Graded Approach?

- EEAE is the competent authority for the control, regulation and supervision in the fields of nuclear energy, nuclear technology, radiological, nuclear safety and radiation protection

  - also for non ionizing radiation, 75 persons, administrative personnel included

- 2009: EEAE requested an international peer review of the national regulatory framework

  - Self Assessment pointed out the need for applying GA. *Weakness in optimization of resources*

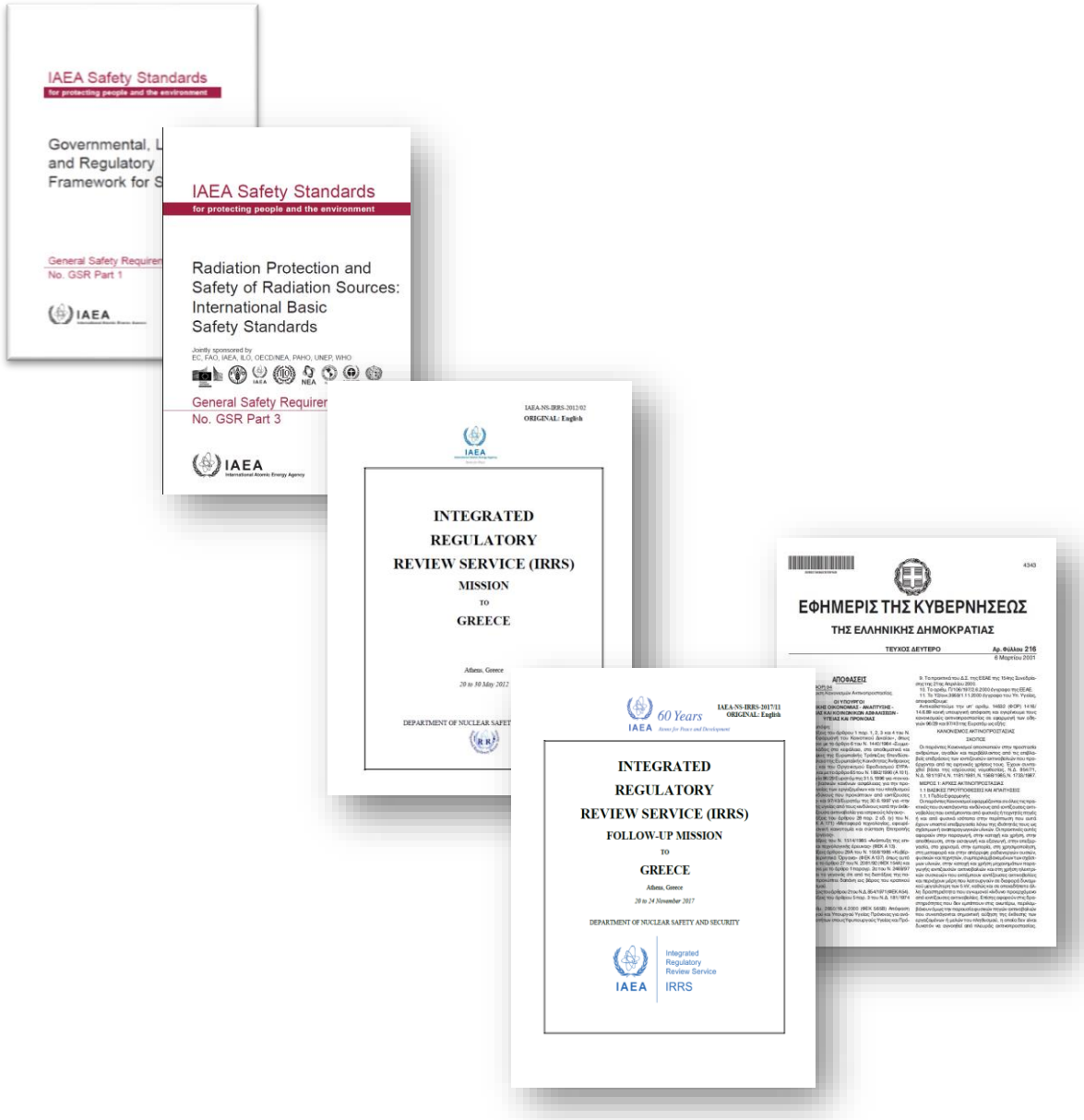
- 2012: The IRRS report mentioned the GA 22 times! In almost all core regulatory processes.

  - *Opportunity to optimize regulatory performance*

- Meanwhile, the European BSS had to be transposed in the national legislation (GA is mainly focused in the regulatory control).

Taking into account:

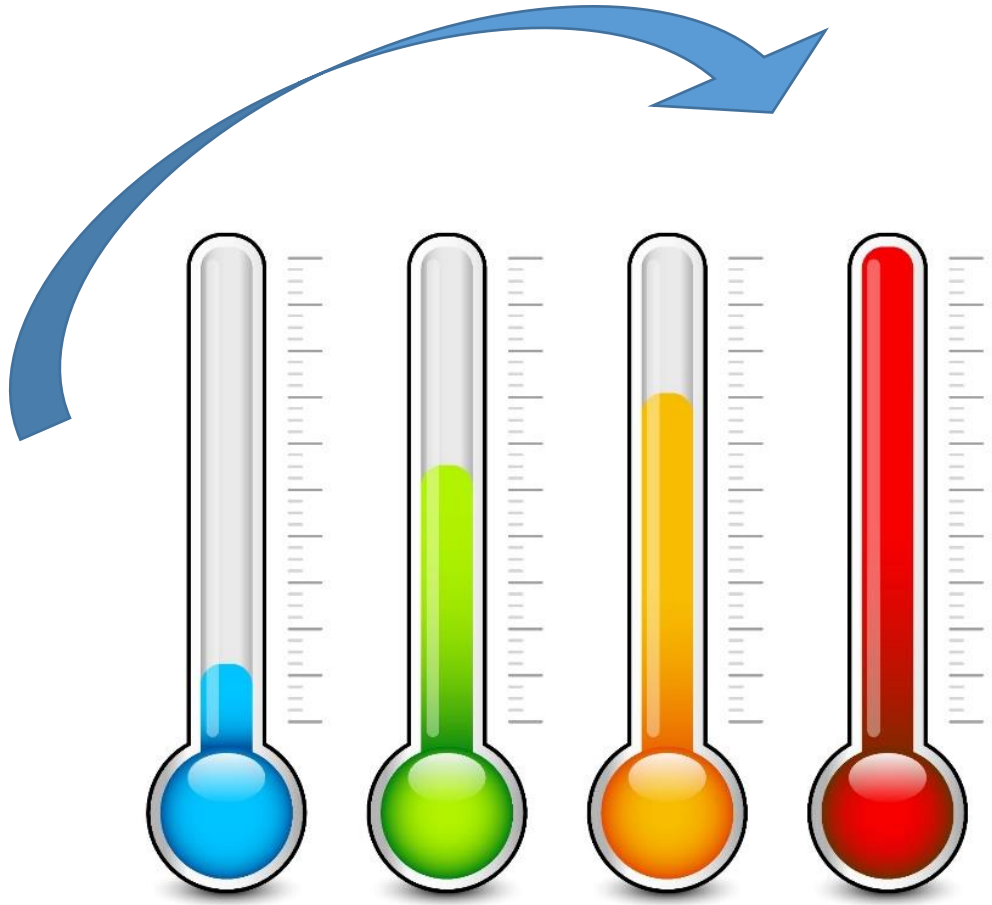
- ✓The IAEA safety standards
- ✓The European BSS
- ✓The results of the peer review missions
- ✓The regulatory experience
- ✓The nature of the country needs:
  - not nuclear
  - small country
  - limited types of practices



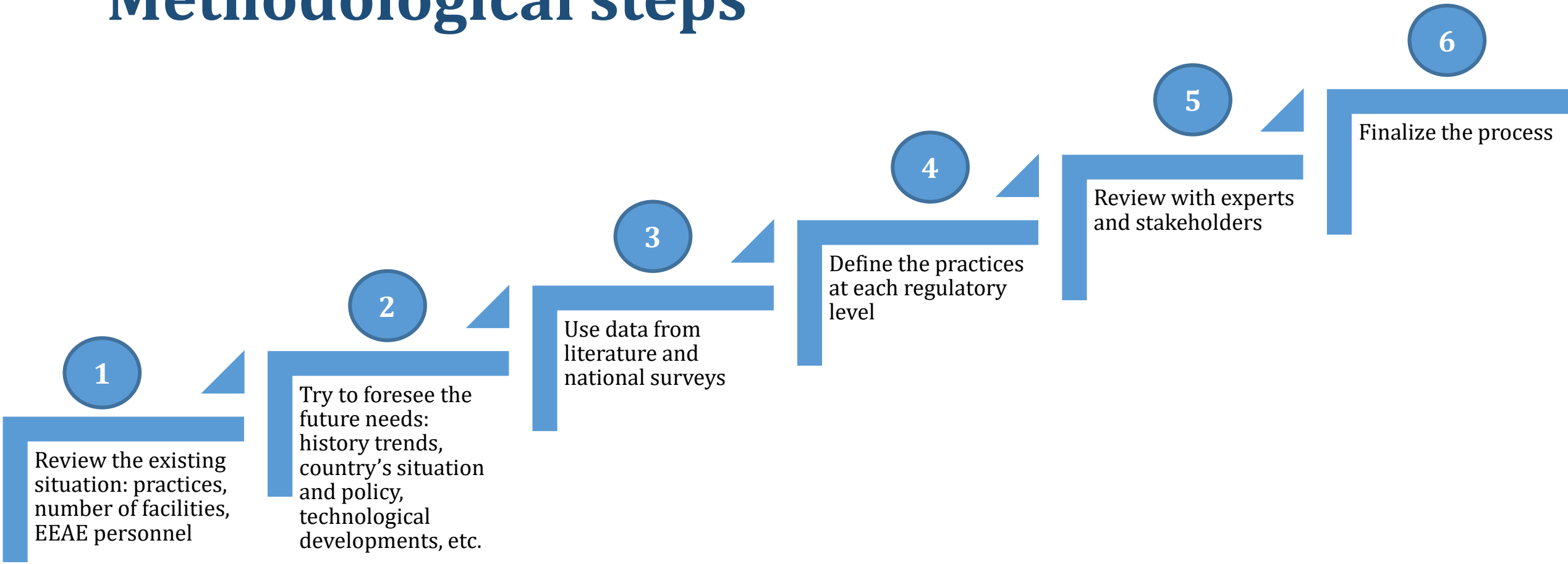
Graded Approach and EEAE's processes

Road map for applying the GA

Regulatory control to be commensurate with the *magnitude* and *likelihood* of exposures resulting from the practice, and commensurate with the *impact* that regulatory control may have in reducing exposures or improving radiological safety



Methodological steps



Data

taken into account

- Complexity of practices:
  - e.g. use of sources in radiation therapy vs dental practices,
- Maturity of practices
  - Tomosynthesis in mammography
- Expected or potential exposures of *public*, workers and patients
- Associated risks

Data

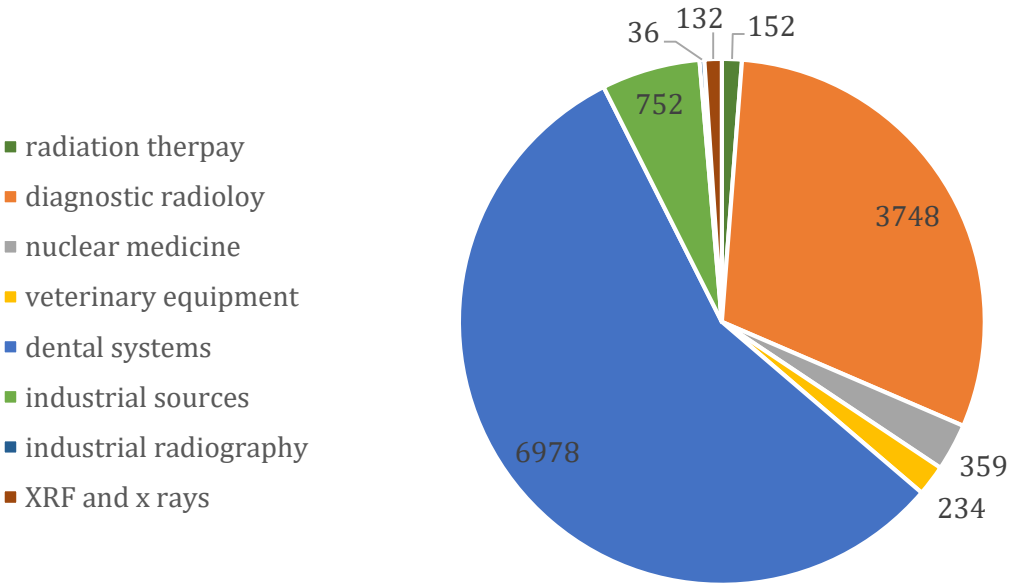
taken into account

- Number of facilities and activities per practice
- Geographical dispersion of facilities and activities
- Previously:
  - One step regulatory control = licensing
  - Inspections linked to licensing

Facilities	number
Radiological facilities	1180
Dental units	6880
Nuclear medicine units	177
Radiation therapy units	31
Veterinary facilities	234
Research and education	219
Industries	307
Radioisotope production	1
Sterilization unit	1

www.eeae.gr

Number of systems per regulatory area

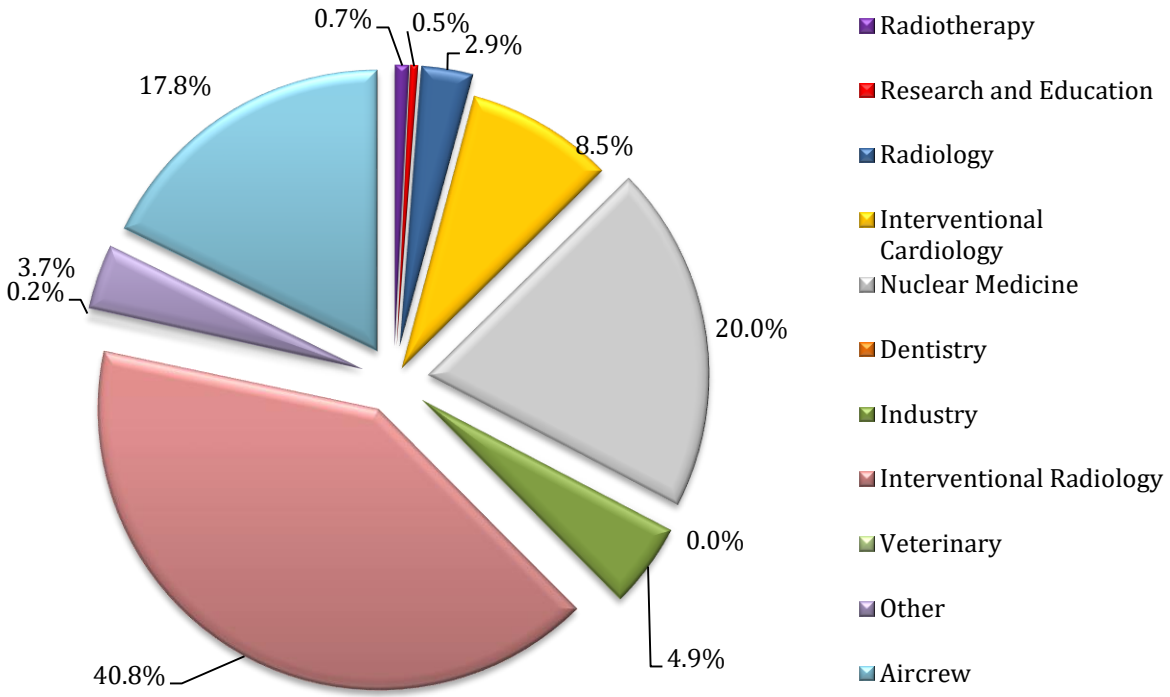


Data

taken into account

- Occupational exposure

Annual dose in mSv per workplace type



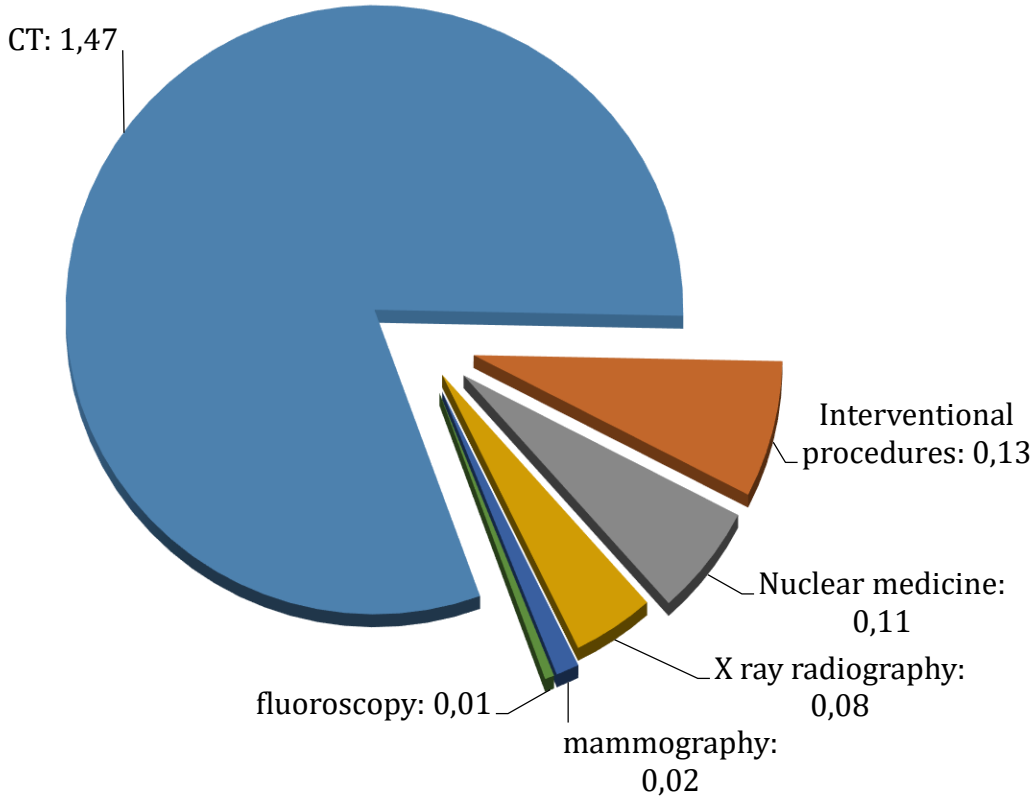
A holistic approach to assessment of population exposure to radiation: challenges and initiatives of a regulatory authority", Health Physics, 115(4):474–489

Data

taken into account

- Medical exposure

Annual mean effective dose (mSv) per individual of the population in Greece from all medical applications using ionizing radiation



A holistic approach to assessment of population exposure to radiation: challenges and initiatives of a regulatory authority", Health Physics, 115(4):474–489

GA

regulatory control

- 1st level: Notification: submission of information to EEAE to notify the intention to carry out a practice
- 2nd level: Authorization

  - ✓Registration: submission of simplified information to EEAE to carry out a practice in accordance with conditions described in the legislation
  - ✓Licensing: submission of information to EEAE to carry out a practice in accordance with specific conditions laid down in the license

GA: practices subject to…

notification

	Practices subject only to notification
1	Working in areas with radon concentration above the national reference level.
2	Existing exposure situations which are of concern from a radiation protection point of view and for which legal responsibility can be assigned
3	Practices with NORM which may lead to presence of naturally-occurring radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways
4	Practices with NORM the concentration of which are higher than the levels of appendix
5	Recycling of residues from the natural radioactive material processing industries in building materials, or disposal, recycling or re use of natural radioactive materials

GA: practices subject to…

registration

	Practices subject to registration
1	Operation of x ray generators for medical exposure involving dental applications (with the exception of dental CT) and bone densitometry
2	Operation of unsealed sources up to **37 MBq** for medical exposure and in vitro diagnostic examinations
3	Operation of x ray generators (<**500 kV**) for non medical purposes and more specifically research, veterinary, industrial, educational and security purposes
4	Operation of radioactive sealed sources of category 5 and unsealed sources up to 37 MBq for non medical purposes and more specifically research, veterinary, industrial, educational and security purposes
5	Practices with NORM, the concentration of which, are 10 times higher than the levels of appendix

e.g. dental procedures, x ray radiographs, RIA assays, vet practices, use of cat. 5 sources for educational purposes etc …

GA: practices subject to…

licensing

	Practices subject to licensing
1	Operation of x ray generators (including accelerators) for medical exposure (except those of point 1 of registration)
2	Operation of radioactive sources for medical purposes
3	Deliberate administration of radioactive substances to persons and animals for medical and veterinary purposes (diagnosis and therapy)
4	Deliberate administration of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products, and the import of such products
5	Operation of x ray generators **(> 500 kV**) and particle accelerators with particle energies **<=10 MeV**, in particular for purposes of research, veterinary, industrial, educational, sterilization and safety, excluding medical exposure purposes
6	Operation of radioactive sources for research, veterinary, industrial, educational, sterilization and safety purposes, excluding purposes involving medical exposure
7	Production of radionuclides using particle accelerators and accelerators> 10 MeV for research and industry purposes

e.g. use of linacs in radiation therapy, use of sources in nuclear medicine, use of sources cat 1 or 2 in industry etc …

GA

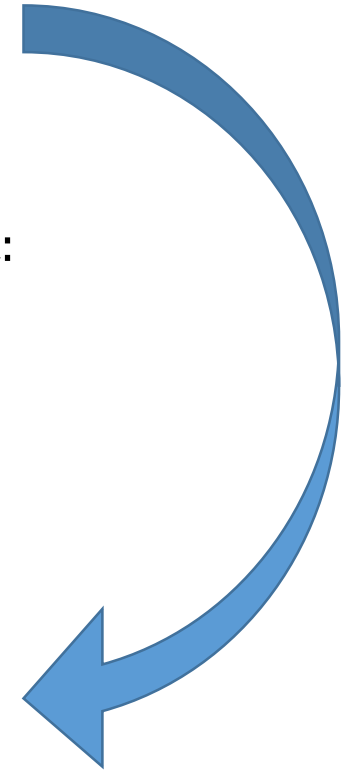
in information to be submitted (registration)

- List of exposed workers
- List of practices and relevant equipment
- Radiation Protection Officer
- Design features of the installation
- Radiological and safety report including (where applicable):
  - expected occupational and public levels of exposure,
  - maintenance and testing programme of equipment,
  - operating limits and dose constraints,
  - management of disused sources

GA

in information to be submitted (licensing)

- List of exposed workers
- List of practices and relevant equipment
- Radiation Protection Officer and Medical Physics expert if applicable
- Design features of the installation
- Radiological and safety report including prepared by a radiation protection expert:
  - operating limits, dose constraints,
  - radiological environmental impact study, where applicable,
  - expected occupational and public levels of exposures
  - individual monitoring and workplace programme,
  - radioactive waste management, management of disused sources
  - accident analysis and emergency procedures;
  - quality assurance program;
  - radiation protection measures and administrative procedures;
  - records and record keeping procedures.



GA

in authorization and resource planning

Taking into account the needs as set by the regulatory control framework

- **Key Performance Indicators** per regulatory process and ionizing radiation application (i.e. industry, research, medical etc.).
  - The percentage of authorization requests completed within a certain period
  - The average response time to requests
- **Budget** (including personnel needs) is drafted and approved by the Board of Directors
- An analysis report is drafted. Corrective actions or optimization measures are taken.

Future of GA in authorization

- Keep the list of practices updated
  - Some types can be moved from the licensing to registration
    (i.e. CBCT or tomosynthesis in mammography)
  - New practices or types of practices to be included in licensing
    (i.e. new radionuclides in nuclear medicine therapy)
- Improvement in the national database to support EEAE processes.
- E-services.


Thank you!