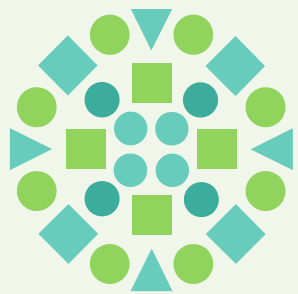


**apa**  
agência portuguesa  
do ambiente

# Portuguese experiences in implementing the graded approach

Pedro Rosário  
Head of Division of Authorization and Nuclear Safety  
Department of Emergencies and Radiation Protection  
[radiacao@apambiente.pt](mailto:radiacao@apambiente.pt)





**apa**  
agência portuguesa  
do ambiente



**Before 2018**



## The previous regulatory framework

- Legal framework was fragmented in multiple decree-laws published in the 90's and early 2000s.
- There was a prescriptive approach having all requirements established in the law:
  - Shielding calculations, Pavement types (e.g. in nuclear medicine)
- Licensing was the only type of authorization used, applicable to all practices.

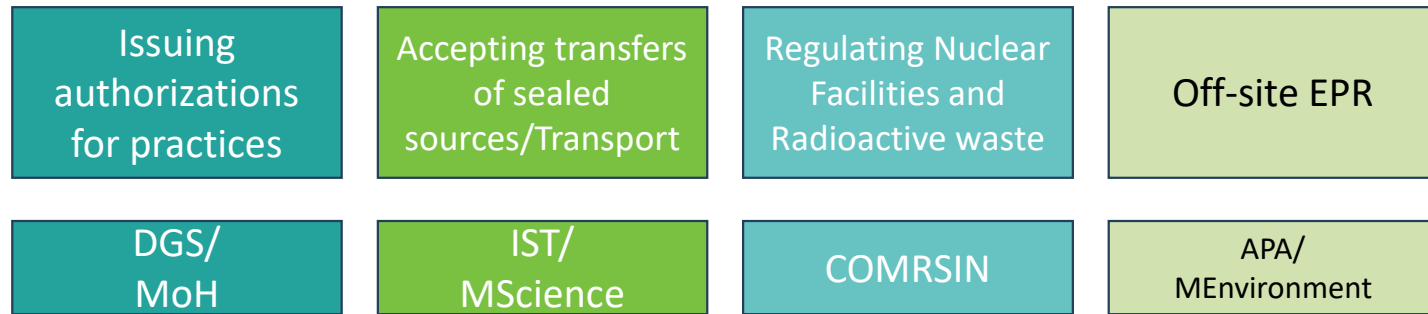


A teal-colored icon consisting of three vertical lines, representing a fence or a barrier.

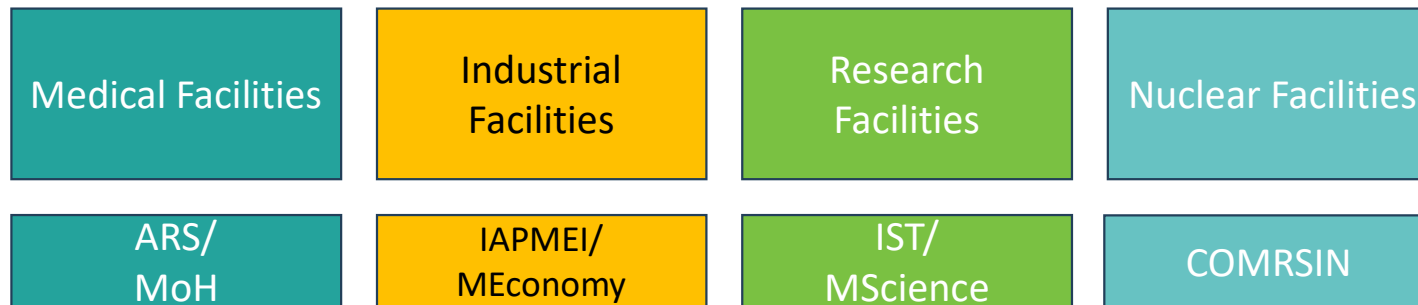


# The previous regulatory framework

- Distributed system, with multiple authorities involved:



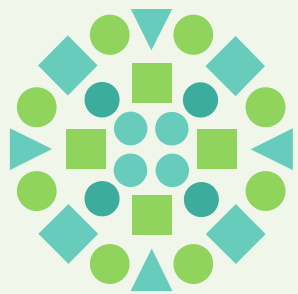
- Multiple inspection authorities:



- Little coordination was done.

- Inspection powers were not executed regularly.





**apa**  
agência portuguesa  
do ambiente

**2018-2019**



# **EU-BSS Directive Transposition and implementation**



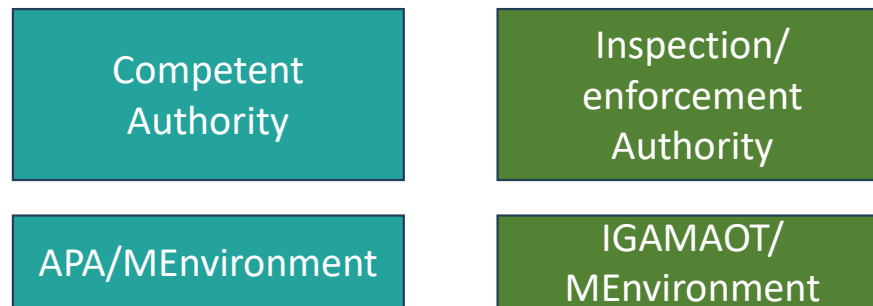
## The Effect of the EU-BSS Directive

- The EU BSS Directive was seen as an opportunity to revise and update the legal Framework.
- A working group was established, comprising experts from MoH, MScience, MEnvironment (the 3 main responsible ministries)
- Working group presented a proposal to the Government.
- Government published DL 108/2018 (consolidated over 7 other decree-laws).



# The Effect of the EU-BSS Directive

- The Regulatory Body reformulated and concentrated in 2 authorities:



- APA and IGAMAOT, ensured effective independence from promoters of the use of ionizing radiation.



## Graded approach

- In authorization :
  - Creation of two levels: registration, licensing.
  - Initial division by type:
    - Registration: Dental intraoral, DEXA.
    - Licensing: remaining practices.
  - Possibility that APA defines which type of authorization is applied to other practices.
    - Encouraged by IRRS Mission results, a risk assessment methodology was established



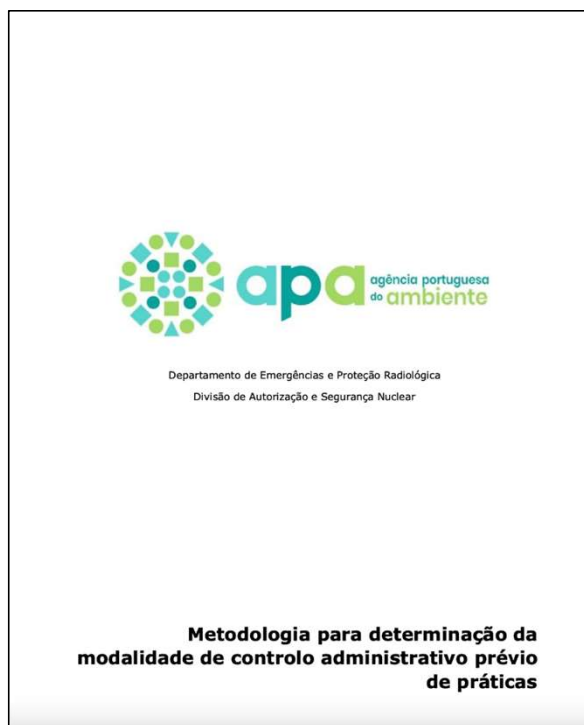
A series of three vertical, slightly curved lines in a light teal color, resembling a stylized 'III' or a decorative element.





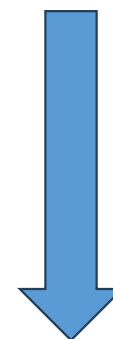
# Graded approach

- Risk assessment based on IAEA TECDOC 1974:



Prática	A prática envolve materiais radioativos	Nível de exposição <sup>1</sup>	Fatores específicos da fonte de radiação <sup>2</sup>	Fatores específicos da prática ou instalação <sup>3</sup>	Risco global da prática <sup>3</sup>	Candidato à modalidade de registo
Operação em local fixo de geradores de radiação para fins de medicina veterinária.	Não	Baixo	Moderado	Baixo <sup>4</sup>	Baixo <sup>4</sup>	Sim
Operação de outros geradores de radiação ou de fontes radioativas para fins de medicina veterinária.	Possível	Baixo	Moderado	Elevado	Moderado	Não
Operação de equipamentos de inspeção de bagagem fixos, cuja fonte de radiação seja um gerador de radiação com tensão máxima até 160 kV	Não	Baixo	Baixo	Baixo	Baixo	Sim
Operação de outros equipamentos de inspeção de bagagem contendo fontes de radiação (tensão acima de 160 kV)	Não	Baixo	Moderado	Moderado	Moderado	Não

- Type of radiation source
- Level of potential exposure
- Radiation source specific factors
- Practice specific factors
- Overall risk



Updated list of practices under registration



## Graded approach

- Updated list of practices under registration, through APA

decision:

- Operation of dental intraoral and cephalometric xrays
- Operation of DEXA equipment
- Operation of fixed veterinary x-rays
- Operation of mobile veterinary x-rays in the conditions established in Professional Society Code of Conduct
- Operation of fixed baggage inspection equipment up to 160 kV
- Operation of XRF equipment using x-rays
- Operation of industrial x-ray equipment for process control up to 150 kV



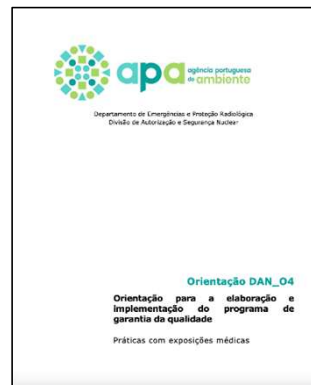
## Graded approach

- In review and assessment:
  - The scope and level of detail of the review of applications takes into account a graded approach:
    - Review of a licensing application more detailed according to the type of practice:
      - Elements reviewed:
        - Safety Assessment
        - Radiation Protection Programme
        - Internal Emergency Plan
        - ...
    - Review of registration applications is focused on *completeness check*.



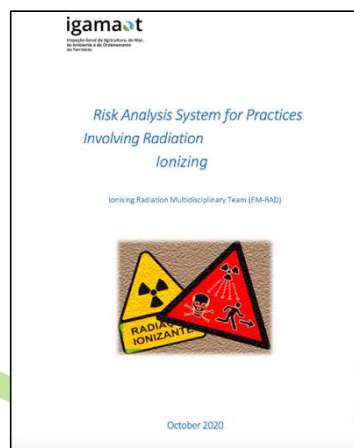
## Graded approach

- In regulations and guides:
  - Requirements in law are general, to be further detailed in guidance documents.
  - Provisions in published guidance documents are more detailed according to the type of practice.
  - Specific guides for different types of practices.
  - APA resources allocated towards new guidance documents according to the needs of the community or immediate gaps that needed addressing.



# Graded approach

- In inspection and enforcement:
  - Learning curve for newly appointed inspection authority, needed to gain experience in lower risk practices.
  - Experience gained led to planning for inspections according with a graded approach - scope, inspection period according to type of practice.
  - Financial penalties for enforcement graded by severity.
    - An enforcement policy was recommended in IRRS Mission.

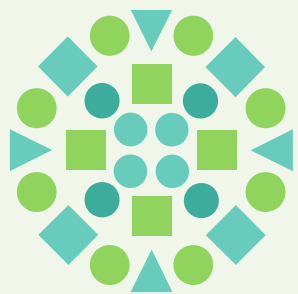


CONCELHO	DISTRITO	TOP	OP - C16	MAX VALOR (C11-C16) Risk - Cl	CI 2 PRÁTICAS DISTINTAS			CI 3 EQUIPAMENTOS			DESEMPENHO DO OPERADOR				CATEGORIA DE RISCO	FREQUÊNCIA INSPEÇÕES (ANOS)	
					Nº	Classe	Risk - Cl 2	Nº	Classe	Risk - Cl 3	VALOR DE RISCO CI (C11-C21) = COB1	Classe	Risk - CDO 1	VALOR DO RISCO CDO = (COB1 + COB2 + COB3) / 3			VALOR DE RISCO (C11 + CDO)
Loures	Lisboa	10 de out	6	6	7	≥ 7	5	16	≥ 16	5	16	Sem CO	-2	-2	14	ELEVADO	2
Castro Verde	Beja		4	3	3-4	3	38	≥ 16	5	12	CO muito grave	2	2	14	ELEVADO	2	
Santarém	Santarém		4	3	3-4	3	16	≥ 16	5	12	CO muito grave	2	2	14	ELEVADO	2	
Coimbra	Coimbra		4	4	3-4	3	40	≥ 16	5	12	CO grave	2	2	14	ELEVADO	2	
Maia	Porto		5	2	2	2	12	10 - 15	4	11	CO muito grave	2	2	13	ALTO	3	
Aljustrel	Beja		4	2	2	2	23	≥ 16	5	11	CO muito grave	2	2	13	ALTO	3	
Lisboa	Lisboa		4	2	2	2	95	≥ 16	5	11	CO muito grave	2	2	13	ALTO	3	
Vila Franca de Xira	Lisboa		4	4	3-4	3	12	10 - 15	4	11	CO muito grave	2	2	13	ALTO	3	
Setúbal	Setúbal		4	2	2	2	33	≥ 16	5	11	CO muito grave	2	2	13	ALTO	3	
Vila Franca de Xira	Lisboa		4	3	3-4	3	13	10 - 15	4	11	CO muito grave	2	2	13	ALTO	3	

## How it was perceived

- Graded approach was designed into the updated legal framework:
  - Established general principles for all practices.
  - Allowed APA to issue regulations and guides establishing lower level requirements.
  - Principles to be implemented in a *graded way*.
- This was not understood by the community:
  - It was seen as “trying to regulate a dentist the same way as an NPP”.
  - **Bafflement** when inspections started being carried out regularly.
- The community preferred a tailor-made framework for each type of practice, instead of the flexibility allowed by the general principles:
  - Checklists, pre-made shielding calculations, templates for RPP,...
- But in most cases, the system was being implemented over the first “license cycle” (5 year).





**apa**  
agência portuguesa  
do ambiente



**2024 onwards**



## Changes in 2022 and late 2023

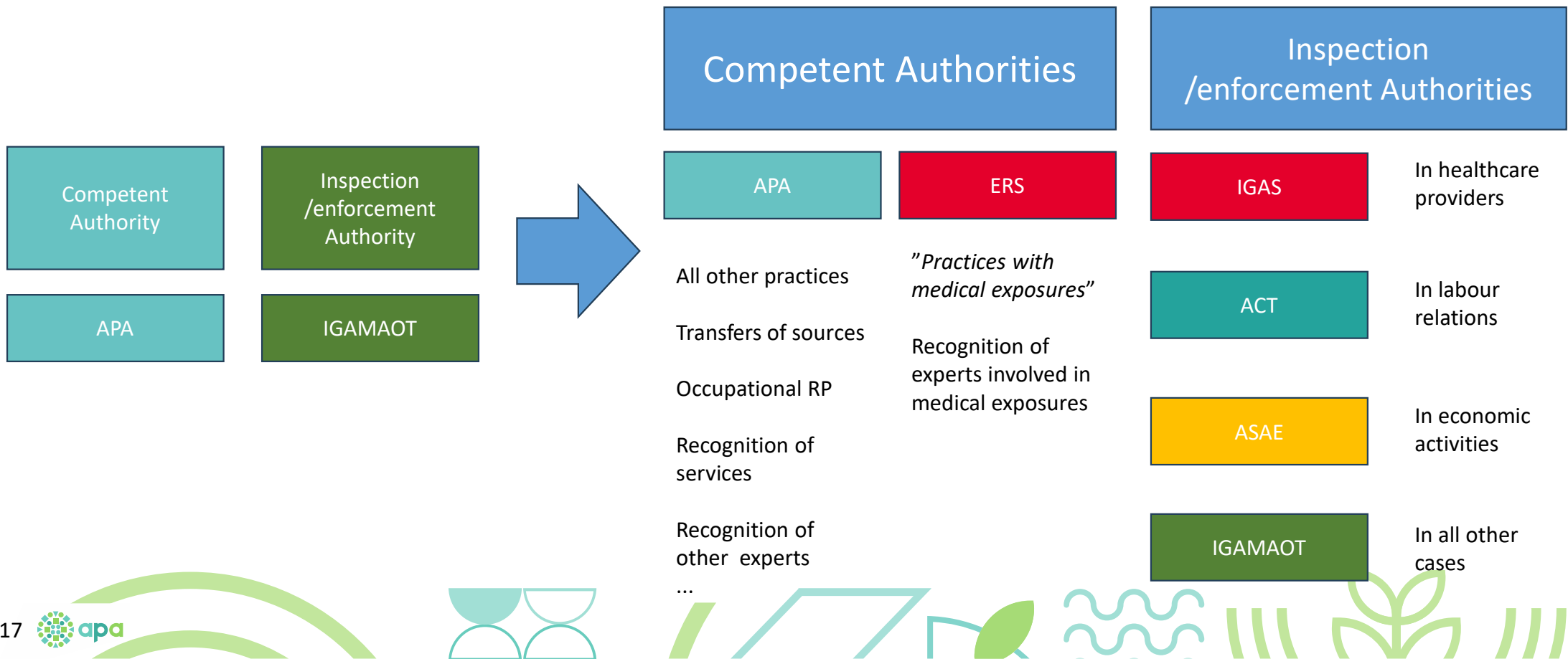
- Amendments to DL 108/2018 were published by the Government in 2022 and late 2023 (DL 81/2022 and DL 139-D/2023), the bulk of which taking effect **from July 1st 2024**.
- Added duplicate article regarding graded approach:
  - **art. 20(2)** – *“Regulatory control (...) must be exercised by the competent authority and the inspection authority, within the scope of their duties, **in accordance with the principle of proportionality, taking into account the magnitude and probability of occurrence of exposures resulting from practices and activities and the impact that such control may have on reducing these exposures or improving radiological safety.**”*
  - **\*NEW\* art. 10-A** – *“Regulatory control (...) must respect a gradual and **proportional approach given the magnitude and probability of occurrence of exposures resulting therefrom, as well as the impact that said control may have on reducing such exposures or improving the safety of facilities.**”*





# Changes in 2022 and late 2023

- Multiple competent authorities, multiple inspection authorities:



## Changes in 2022 and late 2023

- Crystallized the list of practices under registration or licensing in the legal framework and removed the possibility of the regulatory body (APA or ERS) to apply registration or licensing based on their risk assessment and regulatory experience:
  - Risk assessment methodology will be ineffective.
  - Adjustments based on regulatory experience will require changing the legal framework.



## Changes in 2022 and late 2023

- Removed the possibility to apply general criteria for exemption or clearance:
  - No longer possible to use higher values that, for specific applications, are established by the competent authority, satisfying the general exemption and clearance criteria set out in section 3 in ANNEX VII of the Directive.



## Changes in 2022 and late 2023

- Further changes to the specific exemption criteria:
  - **Original art. 23<sup>o</sup>(1)** – “c) *An apparatus containing a sealed radioactive source, provided that:*
    - i) *The apparatus is of a type approved by the competent authority;***
    - ii) *The device does not produce, under normal operating conditions, a dose rate greater than 1 (m)Sv·h (to the power of -1) at a distance of 0.1 m from any accessible surface; and***
    - iii) *The competent authority has specified the conditions for recycling and disposal;*”**
  - **\*NEW art. 23<sup>o</sup>(1)** - “c) *An apparatus that contains a sealed radioactive source, provided that it does not produce, under normal operating conditions, a dose rate greater than 1 (m)Sv·h<sup>-1</sup> at a distance of 0.1 m from any accessible surface;”*

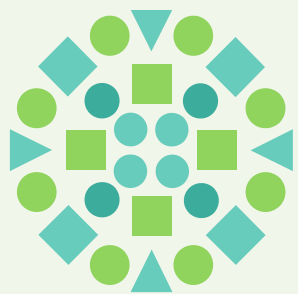
## Changes in 2022 and late 2023

- Revoked the legal framework for education and training.
  - Awaiting publication of new ministerial orders with new requirements for education of RPE's, RPOs and exposed workers.
- Responsibilities of authorized parties using dental intraoral and veterinary x-rays to be specified in ministerial order to be published.
- Templates for Radiation Protection Programmes for each practice to be published in ministerial order.



A teal-colored icon consisting of three vertical lines, representing a list or a signal.





**apa**  
agência portuguesa  
do ambiente



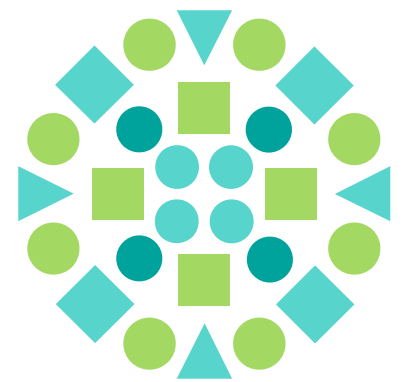
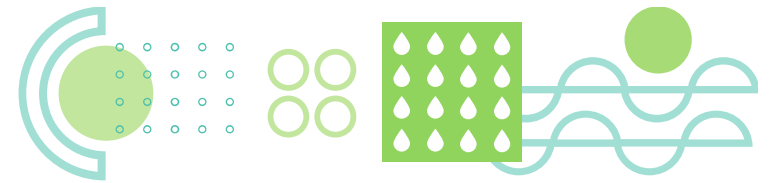
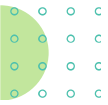
**In conclusion**



# Conclusions

- Graded approach should be part of the legal framework and applied transversely in all regulatory functions.
- Legal framework should be flexible enough to allow the regulatory body to make the necessary adjustments based on regulatory experience.
- Overuse of templates may hinder safety culture.
- Allocate finite resources according to the risk of practices.
  - Simplify procedures for lower risk practices.
  - (...but you can still be overwhelmed with high numbers of applications for these lower risk practices)
- Important tools to consider:
  - Use of technologies to process the workflows.
  - Communicate effectively changes and decisions to all stakeholders.
  - Involve stakeholders in decision-making.
  - Inform and educate the community regarding safety.





**apa**  
agência portuguesa  
do **ambiente**

**THANK YOU!**

[apambiente.pt](http://apambiente.pt)

