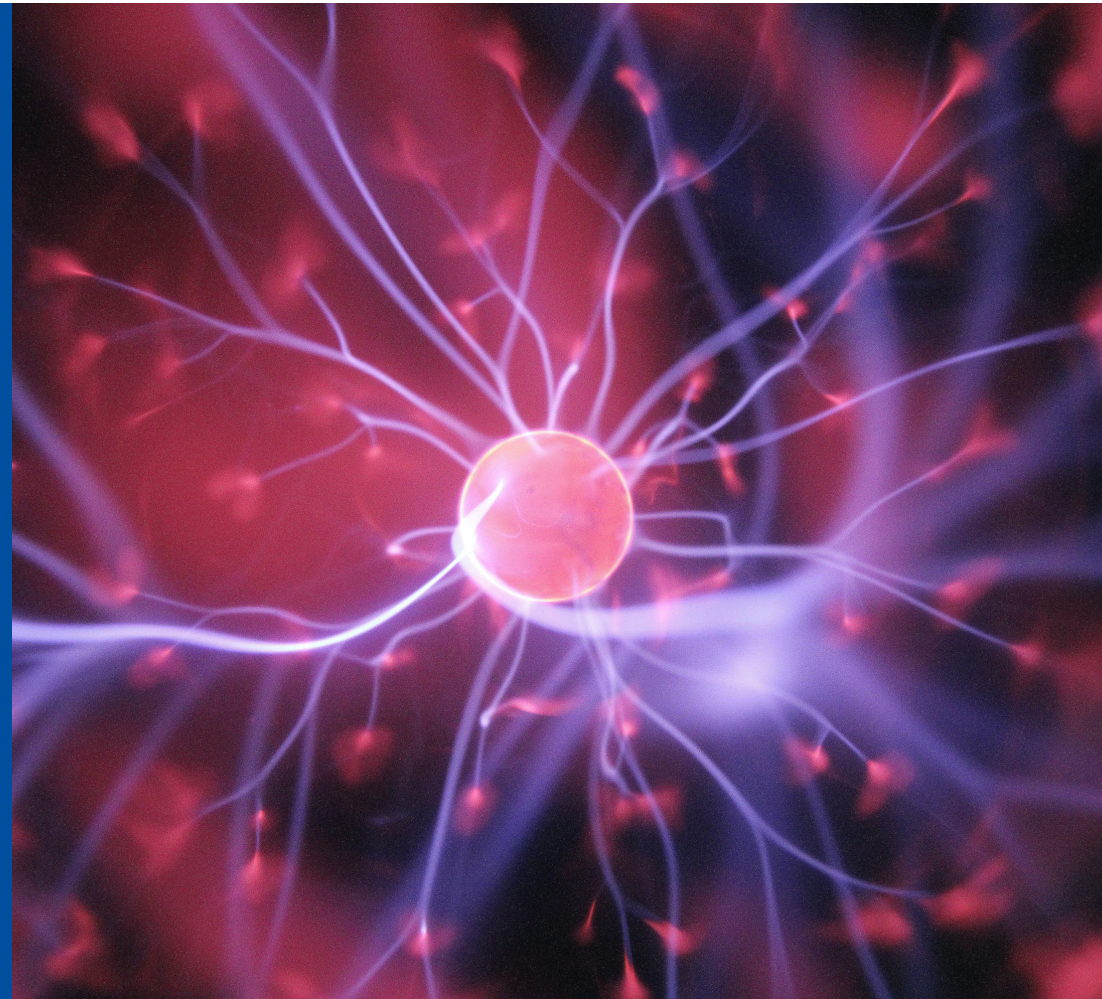


PLAN INVEAT

Challenges for the regulator and the facilities



1. WHAT
2. WHO
3. WHEN
4. HOW

PLAN INVEAT: WHAT

- Government plan to update high technology medical devices in the National Public Health System through the country.
 - INVEAT stands for High Technology Investment
- It is paid for by European funds (**796.100.000 €** - EU Next Generation Recovery Fund)

EQUIPMENT INCLUDED IN INVEAT

EQUIPMENT INCLUDED IN INVEAT	
Linear accelerators (LINAC)	Magnetic Resonance
High Dose Rate Braquithery	Hemodynamics
Radiotherapy planning CTs	Computerized Tomography (CT)
Gammacameras (SPECT/CT)	Vascular Angiography
Hybrid PET/CT	Neurordiological Angiography



PLAN INVEAT: WHAT

OBJECTIVES:

- Replace any device OLDER THAN 12 years, 10 for LINACs and CTs
- Increase by 15% the devices/population ratio for these devices
- Variables:
 - For renovation:
 - age weighted by usage (actual number of exams)
 - only device in hospital
 - reference hospital
 - For new:
 - weighted population



PLAN INVEAT: WHAT

EXAMPLE: LINACS

- LINACS per 100.000 inhabitants RATIO
- TOTAL (246), mean ratio:0,52, highest:0,88, lowest: 0,18



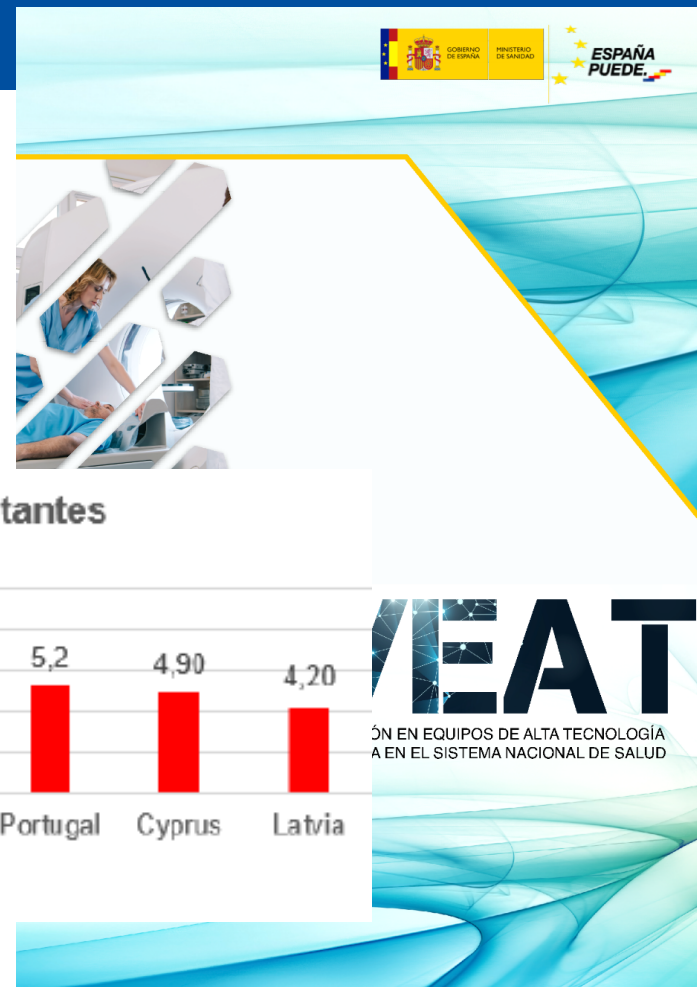
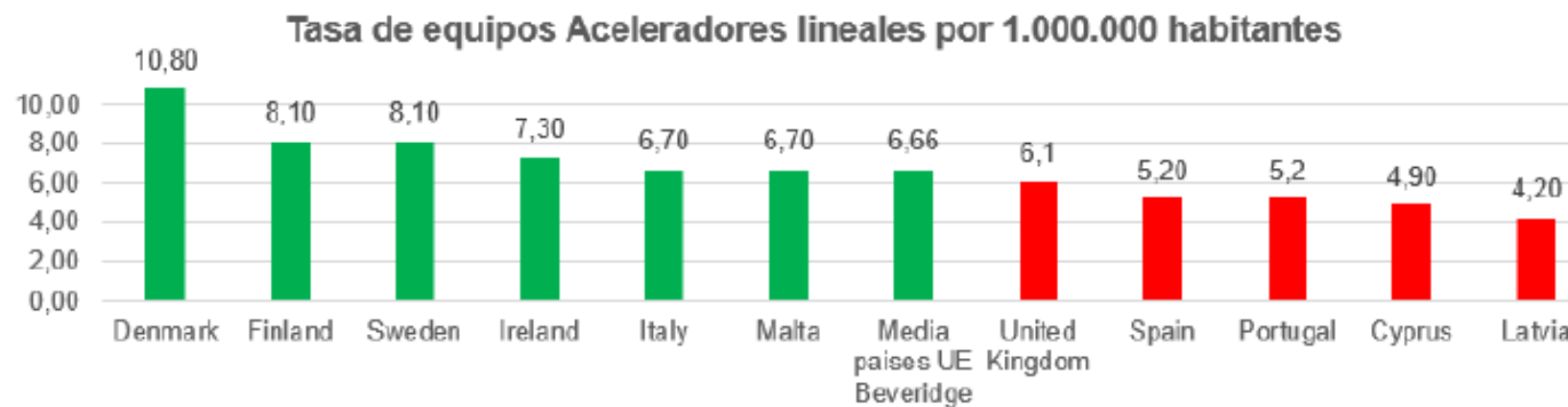
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PLAN INVEAT: WHAT

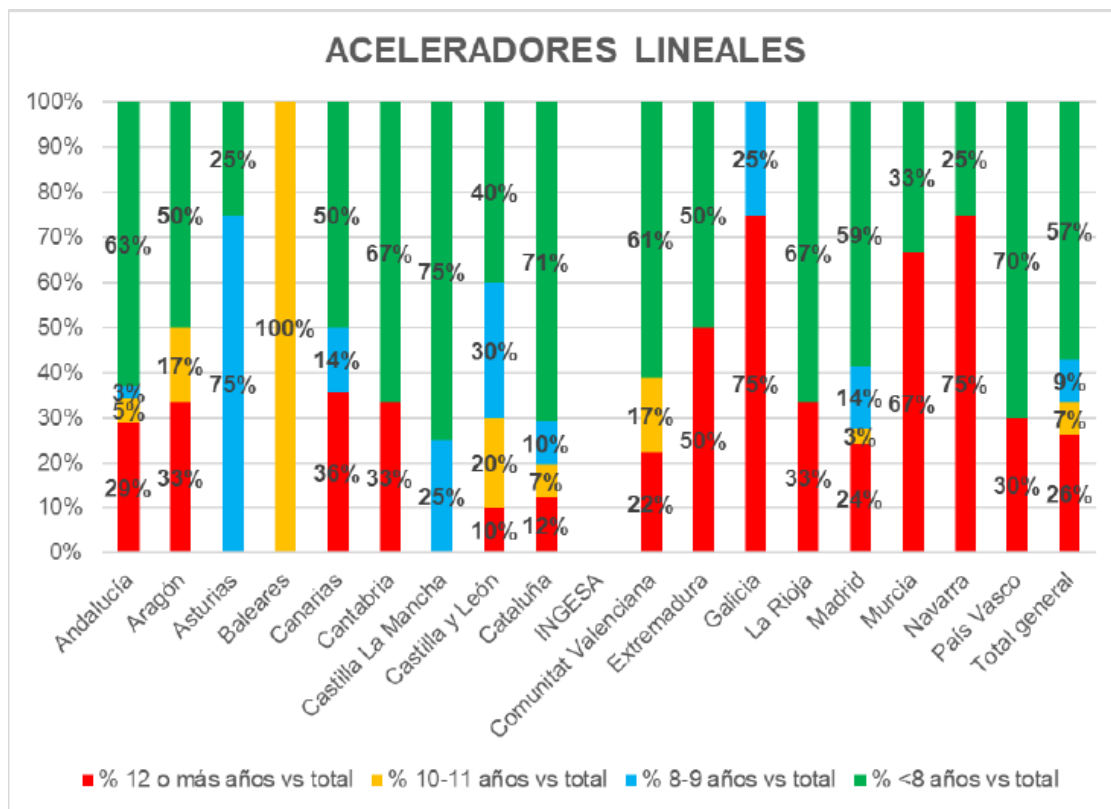
EXAMPLE: LINACS

- LINACS per 100.000 inhabitants RATIO
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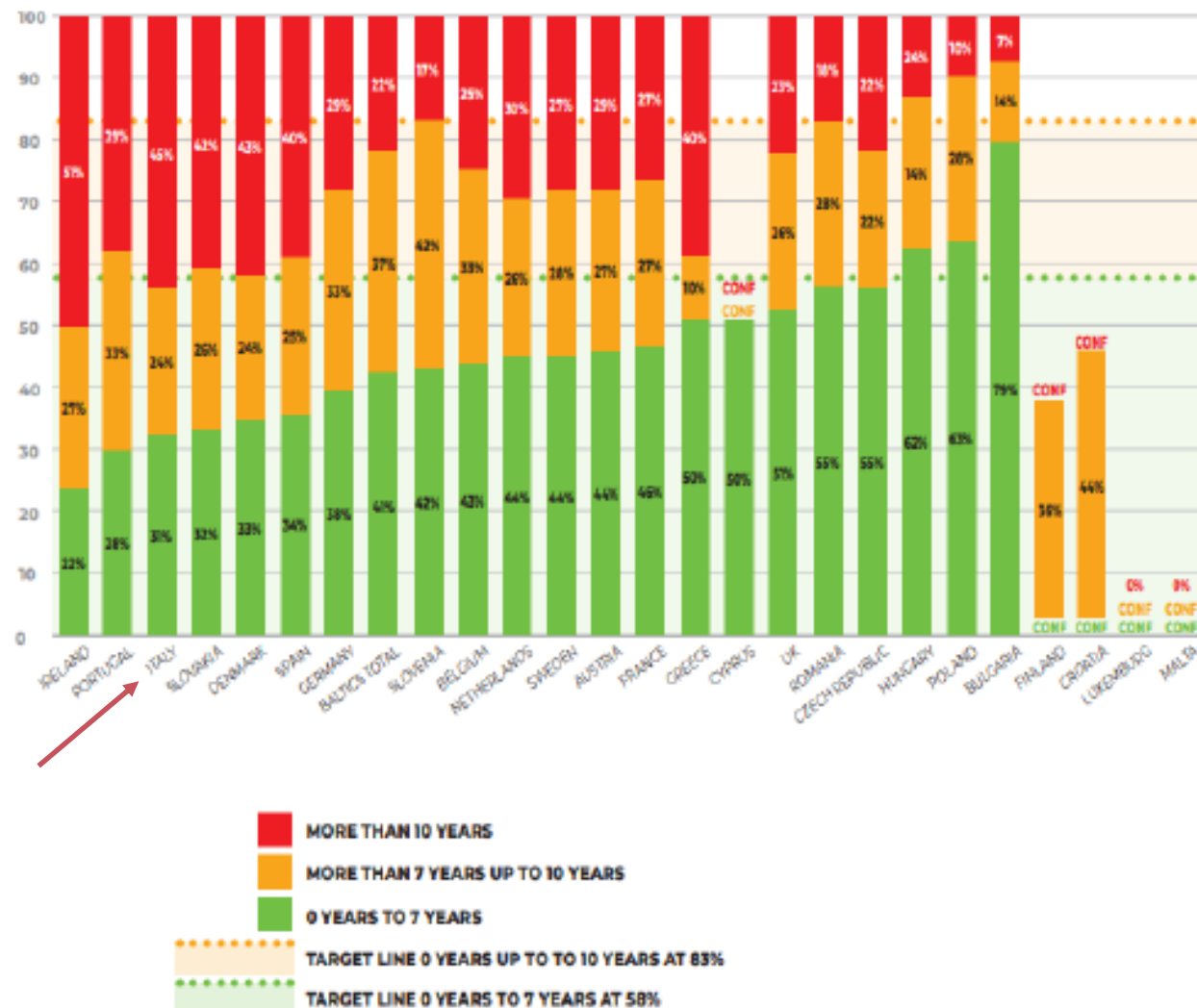
PLAN INVEAT: WHAT

EXAMPLE: LINACS AGE



PLAN INVEAT: WHAT

EXAMPLE: LINACS AGE



- Source: COCIR "Radiotherapy Age Profile & Density December 2019 Edition"13

PLAN INVEAT: WHAT

OBJECTIVES:

- Replace any device OLDER THAN 12 years, 10 for LINACs and CTs
- Increase by 15% the devices/population ratio for these devices



EQUIPMENT INCLUDED IN INVEAT (E= existing PRE INVEAT / N = new / R= replacement / T = total)

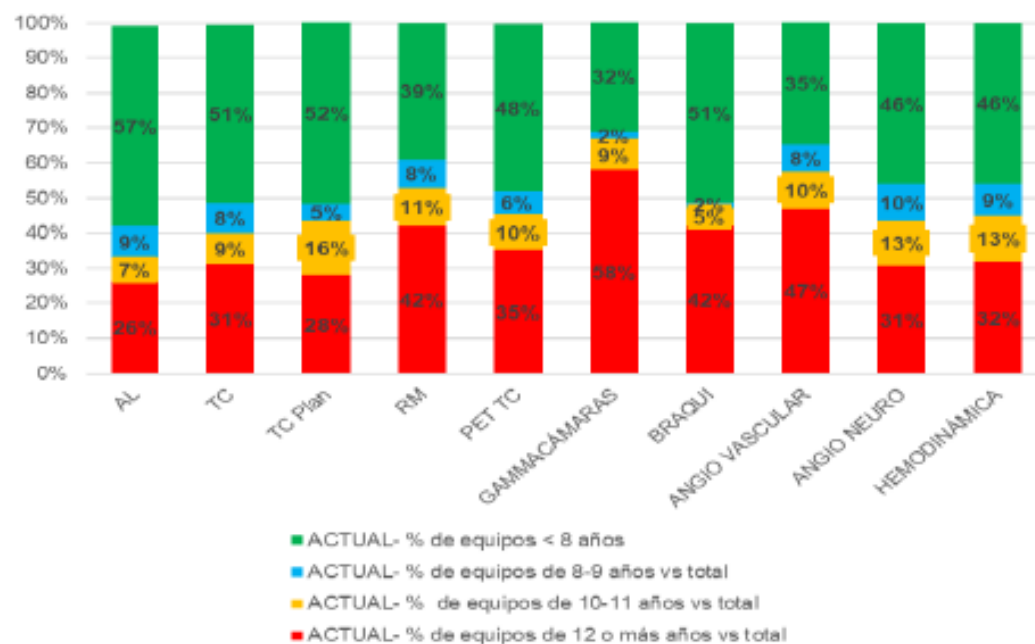
	E	R	N	T		E	R	N	T
Linear accelerators (LINAC)	246	62	24	86	Magnetic Resonance	664	60	89	149
High Dose Rate Braquithery		25	5	30	Hemodynamics	261	55	28	83
Radiotherapy planning CTs		27	7	34	Computerized Tomography (CT)	826	183	36	219
Gammacameras (SPECT/CT)	151	91	12	103	Vascular Angiography	261	52	14	66
Hybrid PET/CT	84	15	30	45	Neurordiological Angiography		15	15	30
TOTALS - REGULATED		220	78	298	TOTALS - UNREGULATED		365	182	547
TOTALS	585	260	845	Roughly 320 medical centers and Hospitals					

PLAN INVEAT: WHAT

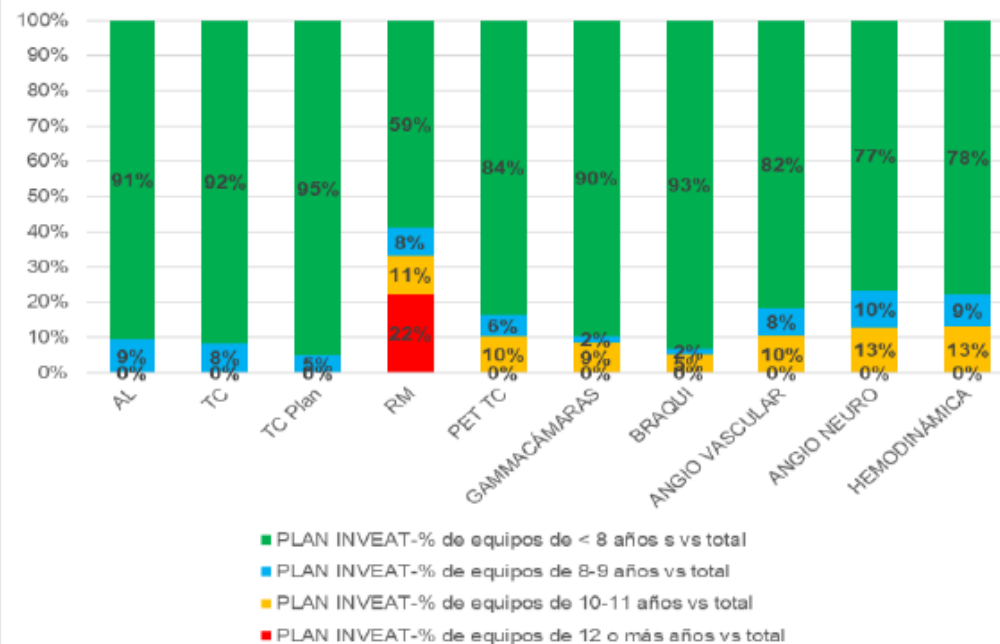
RESULTS:



SITUACIÓN ACTUAL DEL PARQUE TECNOLÓGICO DEL SNS



SITUACIÓN PLAN INVEAT DEL SNS



2 PLAN INVEAT: WHO

- HEALTH MINISTRY
- REGIONAL HEALTH AUTHORITIES (TENDER AND PURCHASE)
- REGIONAL INDUSTRY AUTHORITIES (AUTHORIZATION)
- NUCLEAR REGULATOR (CSN) (AUTHORIZATION)
- MANUFACTURERS
- OVER 300 MEDICAL FACILITIES



3 PLAN INVEAT: WHEN ?????

Between June 30th 2022 and August 31st 2023

??????



4 PLAN INVEAT: HOW ??????????

CHALLENGES

- MANUFACTURERS
 - Planning device delivery to authorized facilities
- HOSPITALS
 - Staggered substitution / long term programming
 - Construction works
 - New personnel
 - New techniques



4 PLAN INVEAT: HOW ??????????

CHALLENGES

- RADIOPROTECTION REGULATOR (CSN)
 - Standardization of applications:
 - Complement existing guide with *standard-formats*

**Formato y contenido estándar de la solicitud de
aceleradores lineales de electrones de uso
médico**

Versión 2
29 de julio de 2022

4 PLAN INVEAT: HOW ??????????

CHALLENGES

- RADIOPROTECTION REGULATOR (CSN)
 - Standardization of applications:
 - Complement existing guide with *standard-formats*
 - Risk graded approach to licensing:
 - New facilities
 - New equipment in existing facilities
 - Replacement requiring major modificacions
 - Replacement not requiring modifications

 Subdirección de Protección Radiológica Operacional	Formato y contenido estándar de la solicitud de aceleradores lineales de electrones de uso médico	Página 39 de 42
		29 de julio de 2022
		Ref.: versión 2

1	2	3	4	3. ESTUDIO DE SEGURIDAD (*)
1	2	3	4	3.1. SISTEMAS DE SEGURIDAD ASOCIADOS A LA INSTALACIÓN Y A LOS EQUIPOS
1	2	3	4	3.2. METODOLOGÍA Y DATOS DE CÁLCULO
1	2	3	4	3.3. RESULTADOS
1	2	3	4	3.4. DETALLES DEL CÁLCULO

1	2	3	4	4. VERIFICACIÓN DE LA INSTALACIÓN
1	2	3	4	4.1. INSTALACIÓN Y ACEPTACIÓN DEL EQUIPO
1	2	3	4	4.2. GARANTÍA, MANTENIMIENTO Y CONTROL DE CALIDAD
1	2	3	4	a. Garantía
1	2	3	4	b. Mantenimiento
1	2	3	4	c. Control de calidad
1	2	3	4	4.3. PROGRAMAS Y PROCEDIMIENTOS DE VERIFICACIÓN
1	2	3	4	a. Programa de verificación de los sistemas de seguridad de la unidad
1	2	3	4	b. Programa de verificación de blindajes
1	2	3	4	c. Programa de calibraciones y verificaciones periódicas de los detectores
1	2	3	4	d. Programa de verificación de la hermeticidad (si aplica)

1	2	3	4	5. REGLAMENTO DE FUNCIONAMIENTO (*)
1	2	3	4	5.1 PERSONAL DE LA INSTALACIÓN
1	2	3	4	a. Organigrama
1	2	3	4	b. Relación de personal
1	2	3	4	c. Responsabilidades
1	2	3	4	d. Clasificación y vigilancia dosimétrica y médica
1	2	3	4	e. Formación en protección radiológica
1	2	3	4	5.2 PROCEDIMIENTOS DE TRABAJO DE LA INSTALACIÓN
1	2	3	4	a. Control de accesos
1	2	3	4	b. Operación del equipo
1	2	3	4	c. Avería del equipo o de sus sistemas auxiliares
1	2	3	4	5.3 REGISTRO Y ARCHIVO
1	2	3	4	a. Anotaciones en el diario de operación
1	2	3	4	b. Archivo de documentos
1	2	3	4	c. Informe anual
1	2	3	4	5.4 SERVICIO O UNIDAD TÉCNICA DE PROTECCIÓN RADIOLÓGICA (si aplica)

4 PLAN INVEAT: HOW ??????????

CHALLENGES

- RADIOPROTECTION REGULATOR (CSN)
 - Standardization of applications:
 - Complement existing guide with *standard-formats*
 - Risk graded approach to licensing:
 - New facilities
 - New equipment in existing facilities
 - Replacement requiring major modificacions
 - Replacement not requiring modifications
 - External support

