



## International Atomic Energy Agency

# Diagnóstico General de la situación en la Región acerca del control regulador

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Department of Nuclear Safety and Security

**INTERNATIONAL ATOMIC ENERGY AGENCY**

# Content

- **Background**
- **Regional Analysis TSA 1**

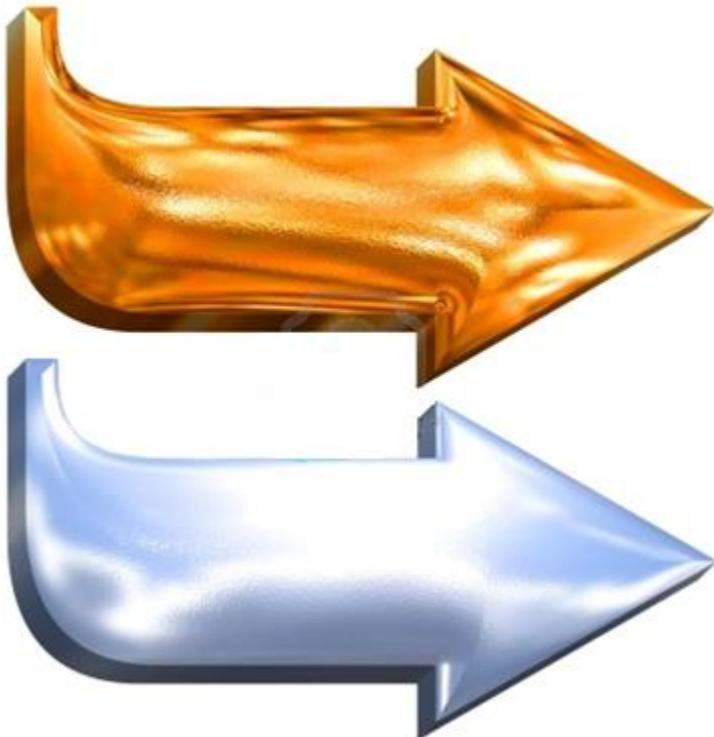
# What to Have Radiation Safety ?

## Complying with the (Board resolutions)



Regulatory Control in Place.

Radiation safety for the workers,  
Patients and Public .



# Examples of harmful effects of radiation

## Late effects

e.g. thyroid and other cancers



“Probabilistic”: Higher radiation dose = higher **risk** of getting cancer

(compare to smoking: more cigarettes = higher risk of getting lung cancer)

## Early effects

- Radiation burns
- Hair loss
- Blood count depression
- Radiation sickness



These ‘**deterministic**’ effects occur only above a certain (high) radiation dose:

Higher dose = worse effect



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# Accidents



# Calidad del servicio



- Personal entrenado.
- Equipo adecuado para el diagnostico o tratamiento especifico.
- Protocolos y procedimientos claros, entrenados y aplicados



## Derechos Humanos

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# Thematic Safety Area 1: National Regulatory Infrastructure

## The foundations of TSA 1 and its 14 elements

- 1. Legislation**
- 2. Regulations and Guidance**
- 3. Regulatory Body Establishment and Independence**
- 4. Regulatory Body Staffing and Training**
- 5. Regulatory Body Funding**
- 6. Coordination and Cooperation at the National Level**
- 7. International Cooperation**
  
- 8. Notification and National Register of Radiation Sources**
- 9. Authorization**
- 10. Inspection**
- 11. Enforcement**
- 12. Safety and Security of Radioactive Sources**
- 13. Information Management**
- 14. Quality Management**

**Principle 2: “An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.”**

The collage includes:

- IAEA Safety Standards for protecting people and the environment**: A blue banner at the top.
- Fundamental Safety Principles**: A section below the banner.
- Jointly sponsored by**: Logos of EASST, FAO, IAEA, ILO, IMO, OECD/NEA, PAHO, UNDP, WHO, IAEA, and WHO.
- Safety Fundamentals No. SF-1**: A document cover.
- IAEA International Atomic Energy Agency**: Logo and text.
- Governmental, Legal and Regulatory Framework for Safety**: A large white box.
- CODE OF CONDUCT ON THE SAFETY AND SECURITY OF RADIOACTIVE SOURCES**: A document cover.
- 放射源安全和保安行为准则**: Text in Chinese.
- CODE DE CONDUITE SUR LA SÛRETÉ ET LA SÉCURITÉ DES SOURCES RADIOACTIVES**: French title.
- КОДЕКС ПОВЕДЕНИЯ ПО ОБЕСПЕЧЕНИЮ БЕЗОПАСНОСТИ И СОХРАННОСТИ РАДИОАКТИВНЫХ ИСТОЧНИКОВ**: Russian title.
- CÓDIGO DE CONDUCTA SOBRE SEGURIDAD TECNOLÓGICA Y FÍSICA DE LAS FUENTES RADIACTIVAS**: Spanish title.
- مدونة قواعد السلوك بشأن أمان المصادر**: Arabic text.
- المشعة وأمنها**: Arabic text.
- IAEA International Atomic Energy Agency**: Logo and text.
- International Atomic Energy Agency**: Text at the bottom right.

# Conceptos Elementales y No negociables

## AUTORIDAD

### Auctoritas



Conocimiento:  
Rigor Técnico y Científico

### Potestas



Reconocimiento:  
Marco Legal

# Conceptos Elementales y No negociables

## INDEPENDENCIA

Respeto institucional

Respeto Autoridades  
Nacionales

Respeto de los Titulares de  
Licencias

Recursos suficientes para su  
función



# Conceptos Elementales y No negociables

## GESTIÓN

Plan de Trabajo Optimizado



Basado en Riesgo

1. Desarrollo normativo
2. Autorizaciones
3. Inspecciones
4. Acciones correctoras
5. Seguimiento de incidentes
6. Reportes a las autoridades nacionales
7. Evaluaciones externas: Calidad (nacional) + (Internacional )

# Conceptos Elementales y No negociables

## COLABORACIÓN

Autoridades nacionales => Asesoramiento normativo  
Planificación y respuesta ante emergencias

Titulares de licencias => Guías y recomendaciones

Público => Información sobre instalaciones, sucesos, seguridad...

Sociedades Profesionales : Divulgación científica

Internacional => OIEA, FORO, ARCAL...

# 3 Dificultades

## Otras Prioridades gubernamentales

Limita los recursos económicos y humanos

## Corrientes políticas

12 jefes de AR- LA, han cambiado en los últimos 3 años

## Dificultad para aprobar documentos

- 5 años para aprobar una ley
- 3 años para un reglamento



# TSA 1: Legal and Regulatory Infrastructure

Ensuring appropriate legislation and regulations in addition to an effectively independent regulatory body, with sufficient staffing and funding, which is empowered to conduct its regulatory functions effectively.



# Responsabilidades en Regulación en A.L.

Argentina

Belize

Bolivia

Brasil

Chile

Colombia

Costa Rica

Cuba

Ecuador

El Salvador

Guatemala

Haiti

Honduras

Jamaica

Mexico

Nicaragua

Panama

Paraguay

Peru

Republica Dominicana

Uruguay

Venezuela

MinSalud y Otros 9



Solo MinSalud 7



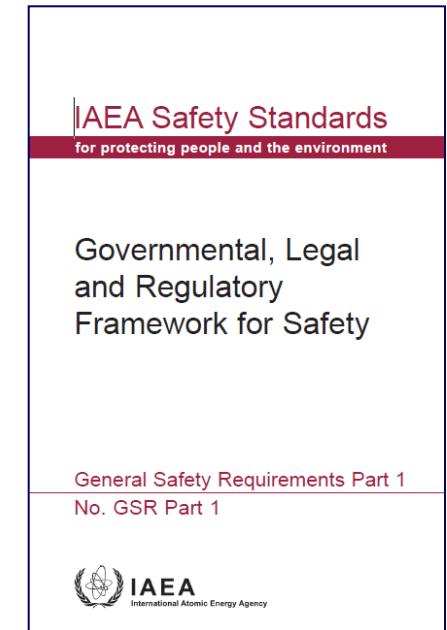
No Min Salud 6



# Thematic Safety Area 1: National Regulatory Infrastructure

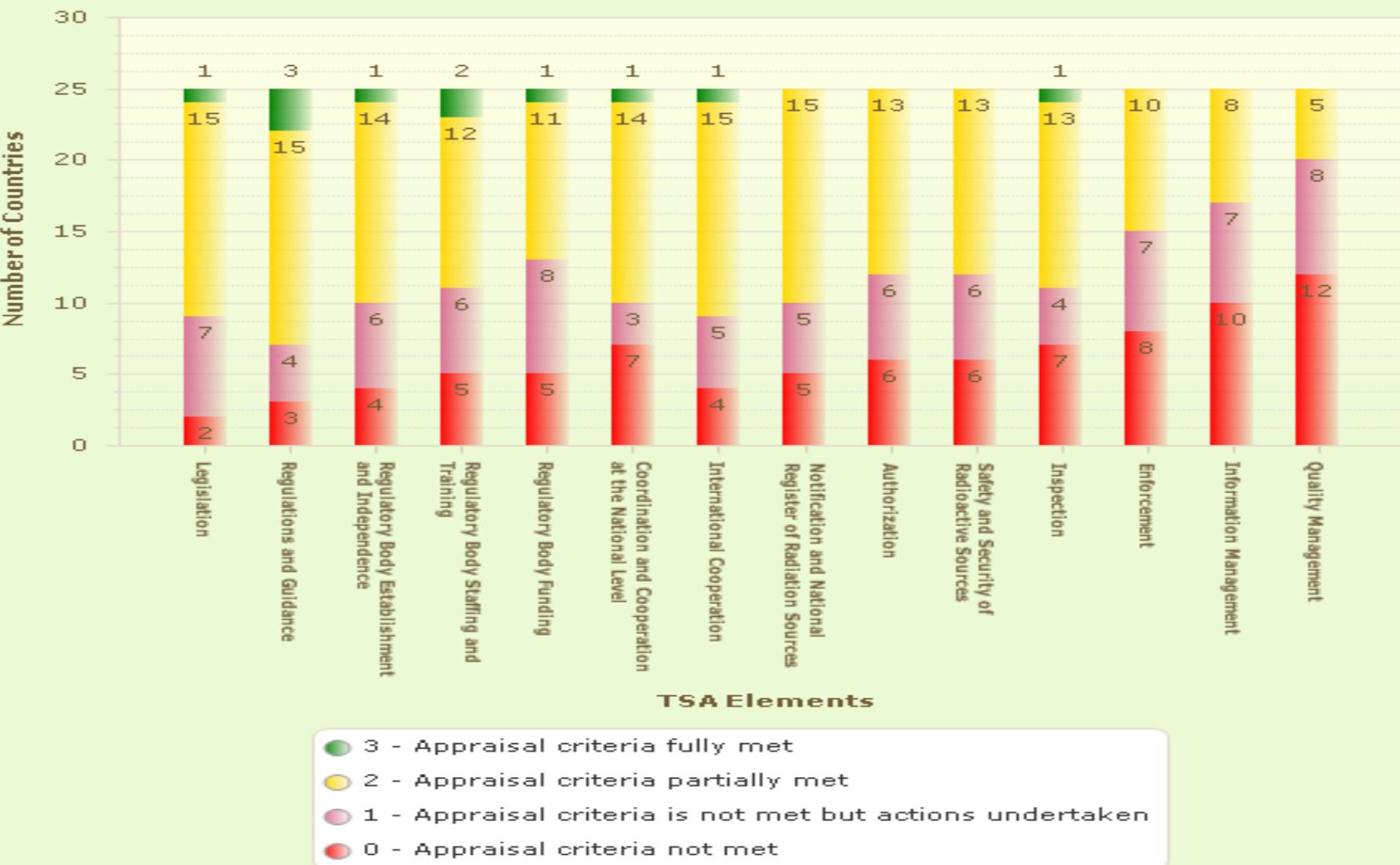
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# Abril 2015 Regional Status TSA 1

## Achievement towards Establishing Infrastructure Elements for all PI in Latin America - TSA1



# **Key Elements TSA 1**

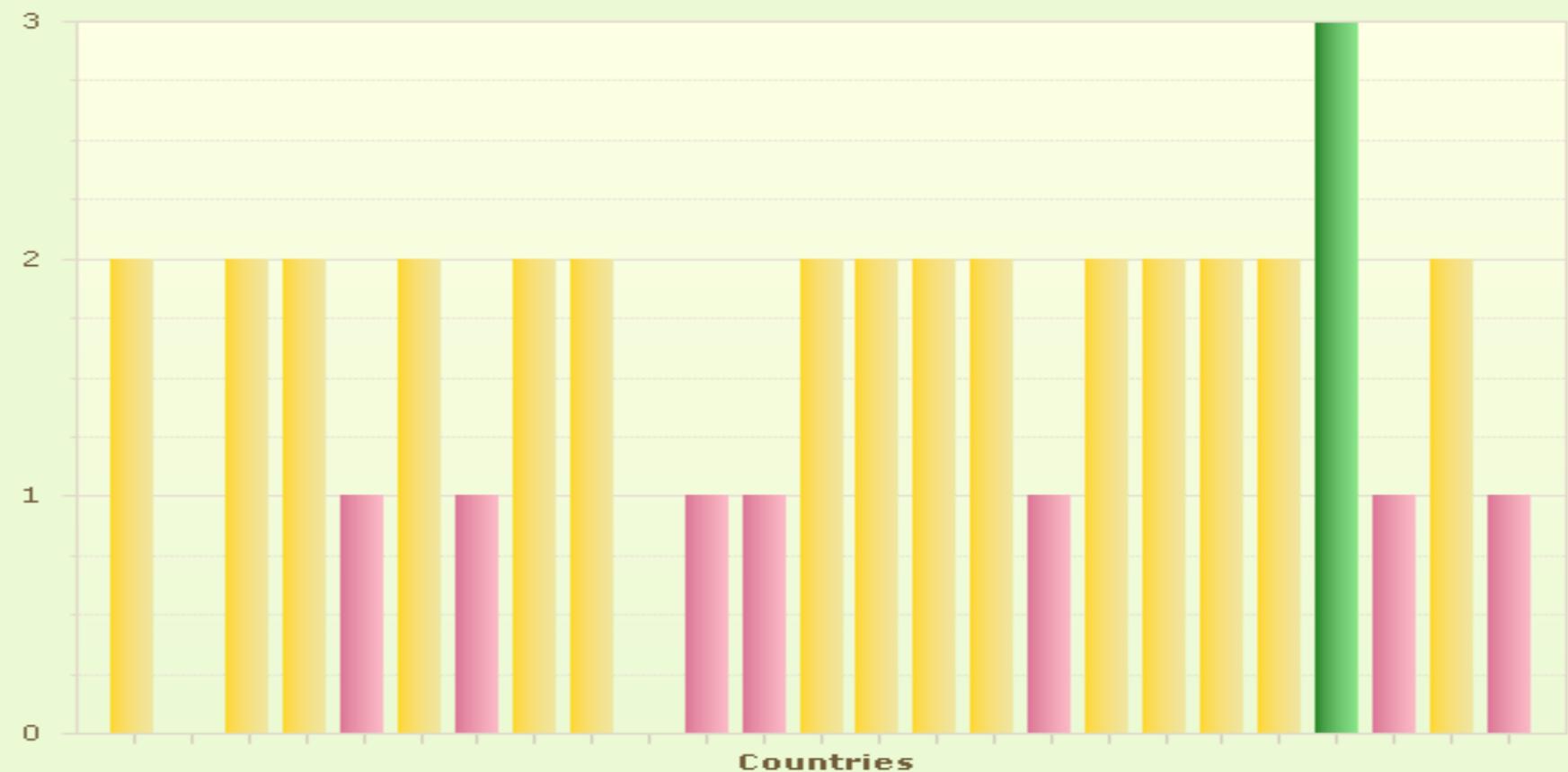
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- 6. Inspection**
- 7. Enforcement**



# Legislation

32 %

## Country Comparison By Elements in Region Latin America TSA1-1-Legislation



- 3 - Appraisal criteria fully met
- 2 - Appraisal criteria partially met
- 1 - Appraisal criteria is not met but actions undertaken
- 0 - Appraisal criteria not met

## International School of Nuclear Law

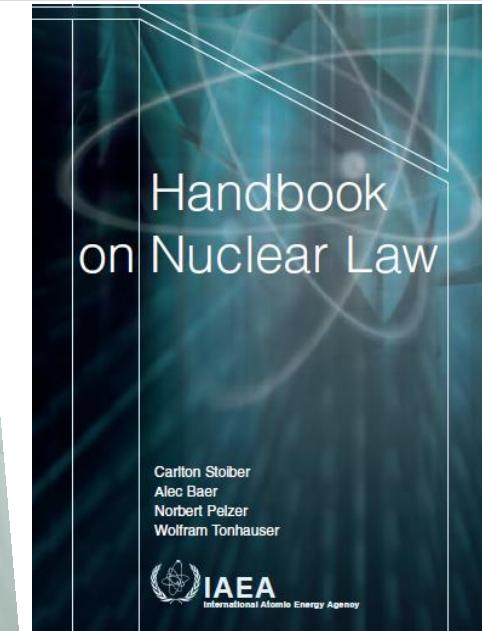
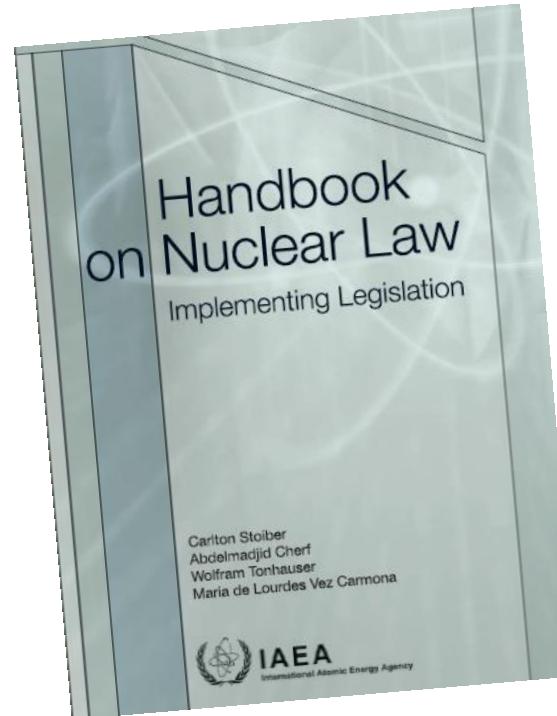
2015 summer session:

**24 August to 4 September 2015**

Application deadline: 17 April 2015

Misiones de expertos

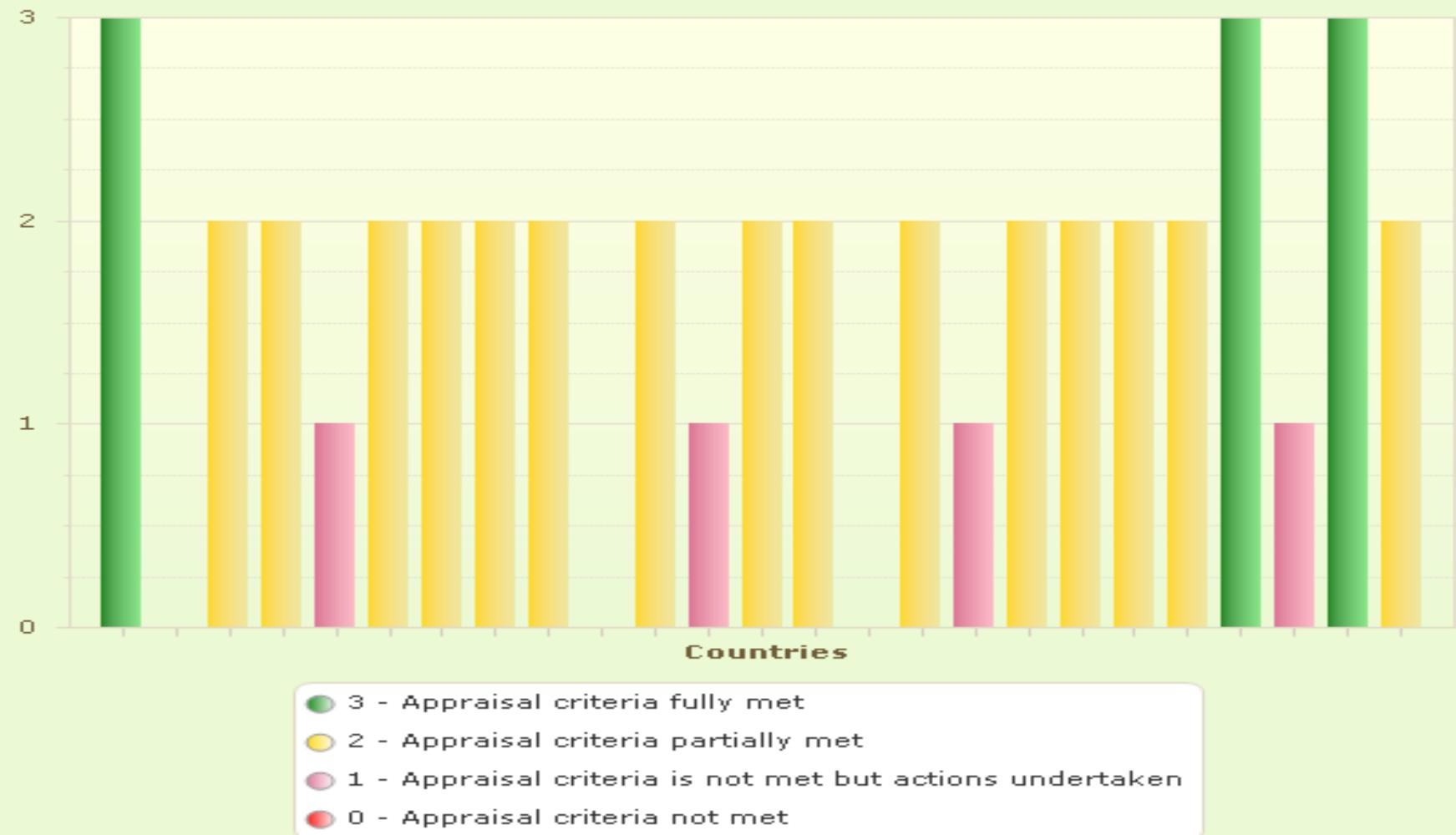
Reuniones regionales



# Regulation and Guidance

30%

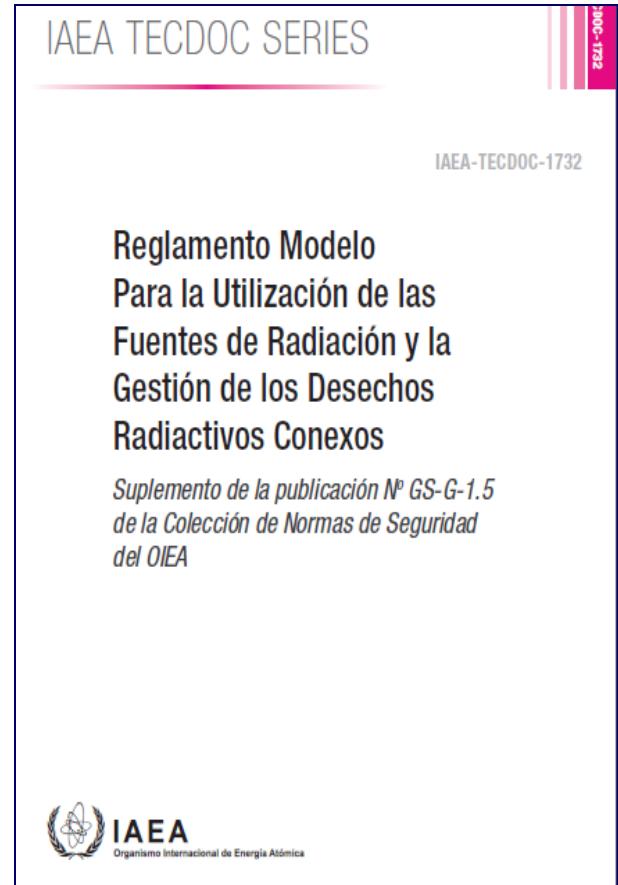
## Country Comparison By Elements in Region Latin America TSA1-2- Regulations and Guidance



# Regulations and Guidelines

- Basic safety Standards
- Authorizations
- Waste Safety
- Transport Safety.
- Specific regulations

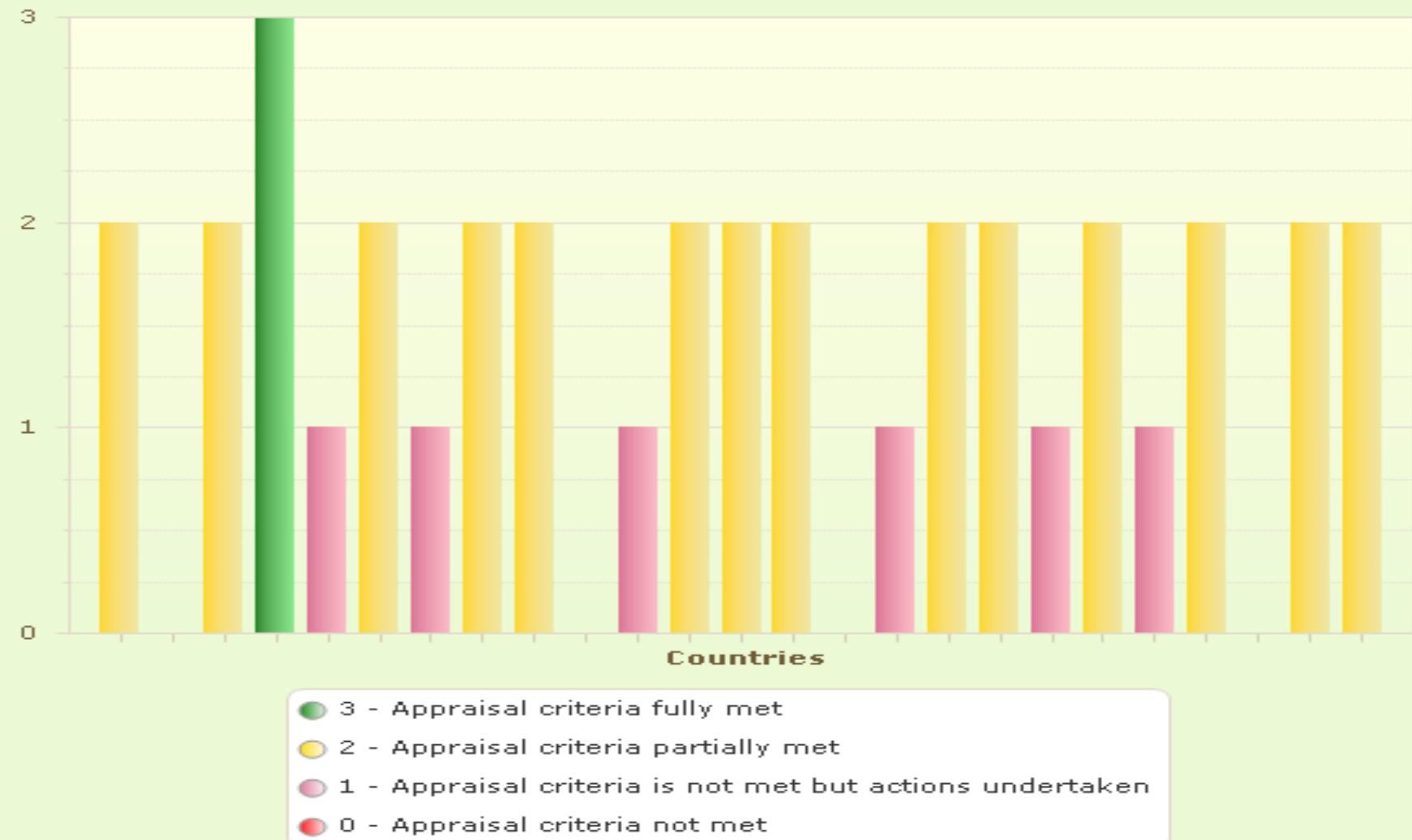
- School of drafting regulations.
- Expert missions
- IT tool -Gap analysis (against the Safety Standards)



# Establishment of the regulatory Body

30%

Country Comparison By Elements in Region Latin America  
TSA1-3-Regulatory Body Establishment and Independence



# Establishment of the regulatory Body

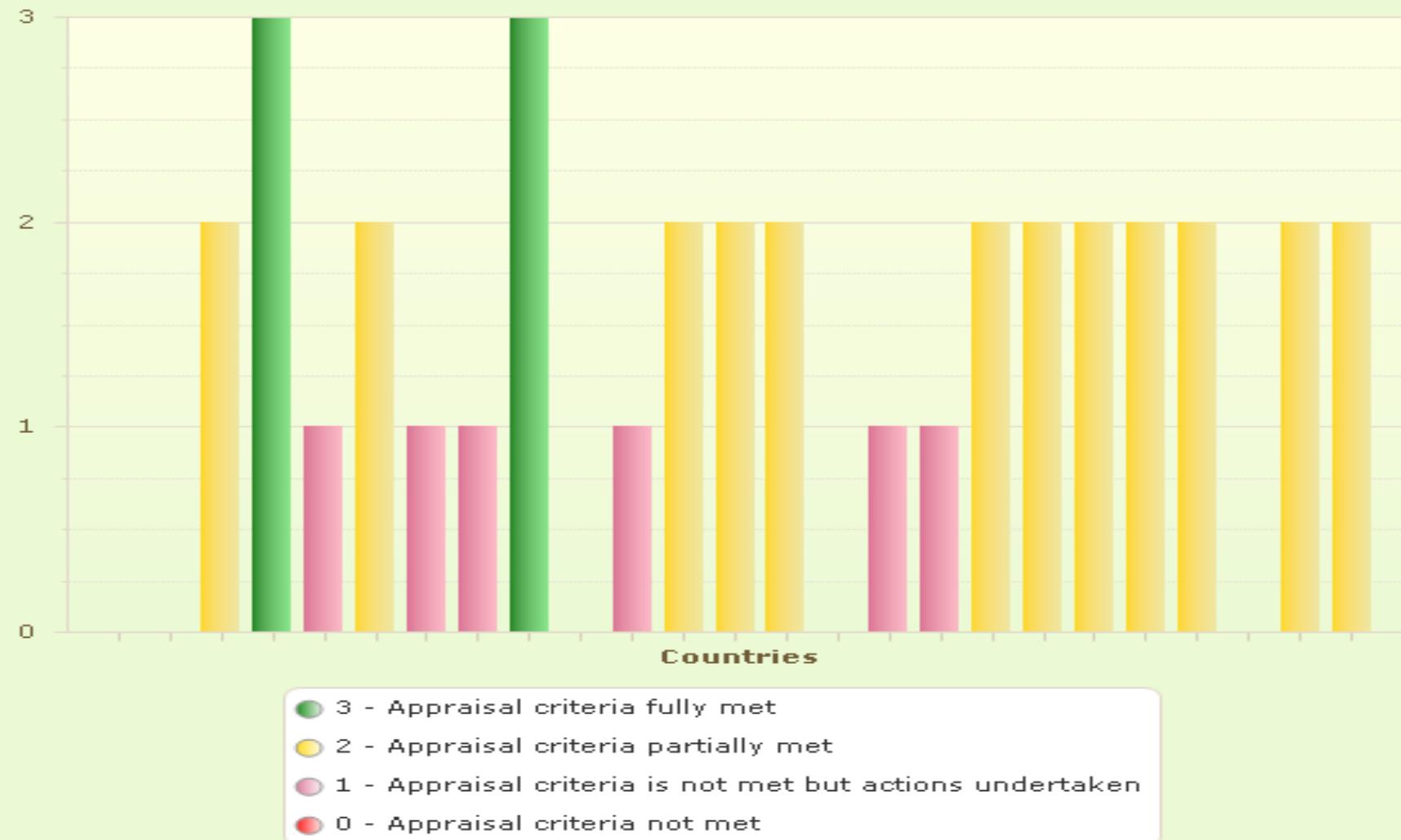
- Awareness missions to politicians.
- Communication strategy .
- Safety Guide is been developed



# Staff of the RB

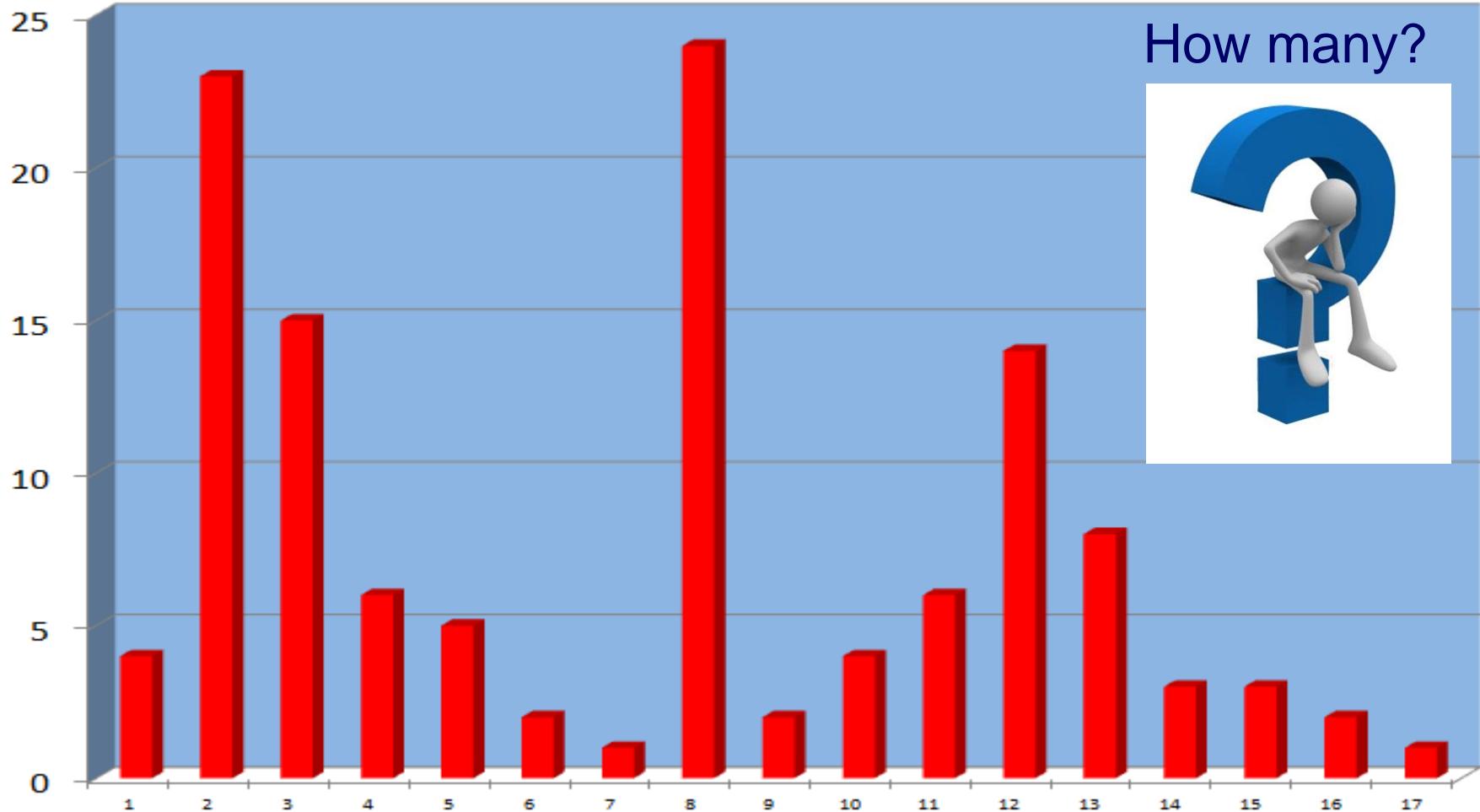
40%

## Country Comparison By Elements in Region Latin America TSA1-4- Regulatory Body Staffing and Training



# Staff of the RB

40%



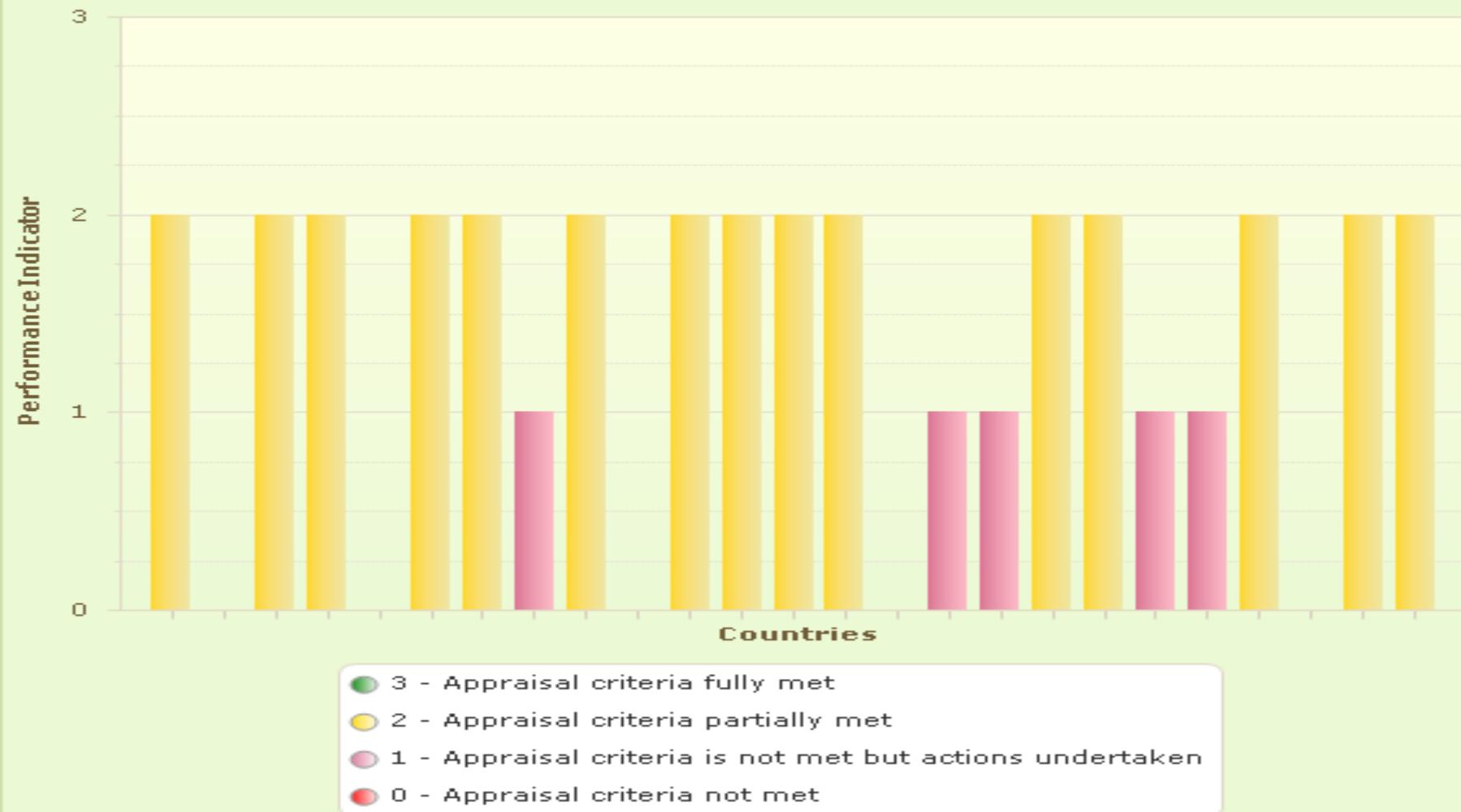
How many?



# Inventory of sources

40%

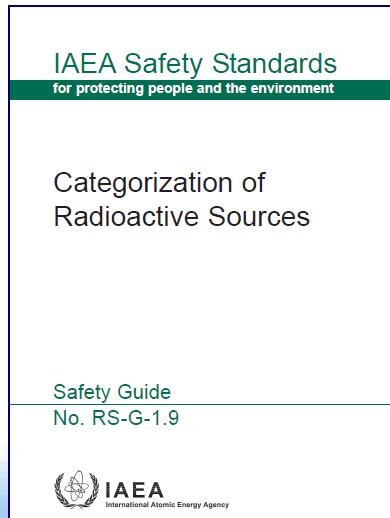
## Country Comparison By Elements in Region Latin America TSA1-8- Notification and National Register of Radiation Sources



# Inventory of sources

40%

- 70% MsS have a register for Category 1-2 and 3.
- 90% MSs do not have a complete register for X-Ray practices .
- Support IT Systems



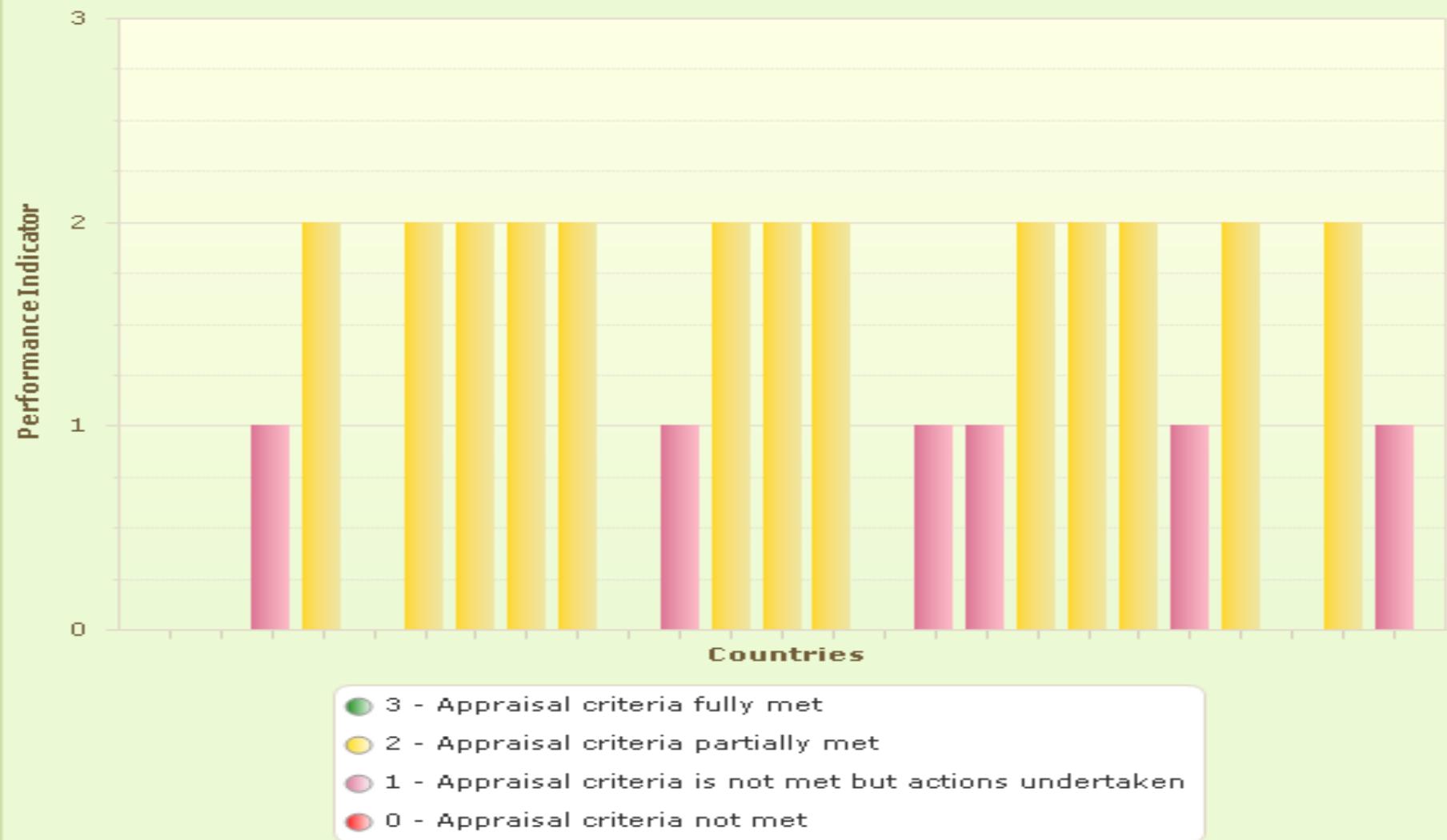
Category	Source <sup>a</sup> and practice	Activity ratio <sup>b</sup> (A/D)
1	Radioisotope thermoelectric generators (RTGs) Irradiators Teletherapy sources Fixed, multi-beam teletherapy (gamma knife) sources	$A/D \geq 1000$
2	Industrial gamma radiography sources High/medium dose rate brachytherapy sources	$1000 > A/D \geq 10$
3	Fixed industrial gauges that incorporate high activity sources <sup>c</sup> Well logging gauges	$10 > A/D \geq 1$
4	Low dose rate brachytherapy sources (except eye plaques and permanent implants) Industrial gauges that do not incorporate high activity sources <sup>c</sup> Bone densitometers Static eliminators	$1 > A/D \geq 0.01$
5	Low dose rate brachytherapy eye plaques and permanent implant sources X ray fluorescence (XRF) devices Electron capture devices Mossbauer spectrometry sources Positron emission tomography (PET) check sources	$0.01 > A/D$ and $A > \text{exempt}^d$



# Authorization

48%

## Country Comparison By Elements in Region Latin America TSA1-9-Authorization



# Authorization

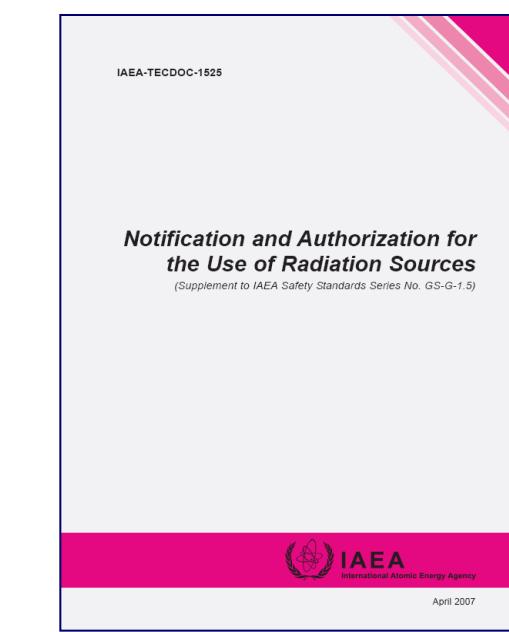
48%

75 % de equipos de Rayos X no están bajo un control regulador en la Región .

42 LINACs no están bajo un control regulador en 7 países .

90% de Cobaltos están licenciados

85% de los servicios de medicina Nuclear están licenciados

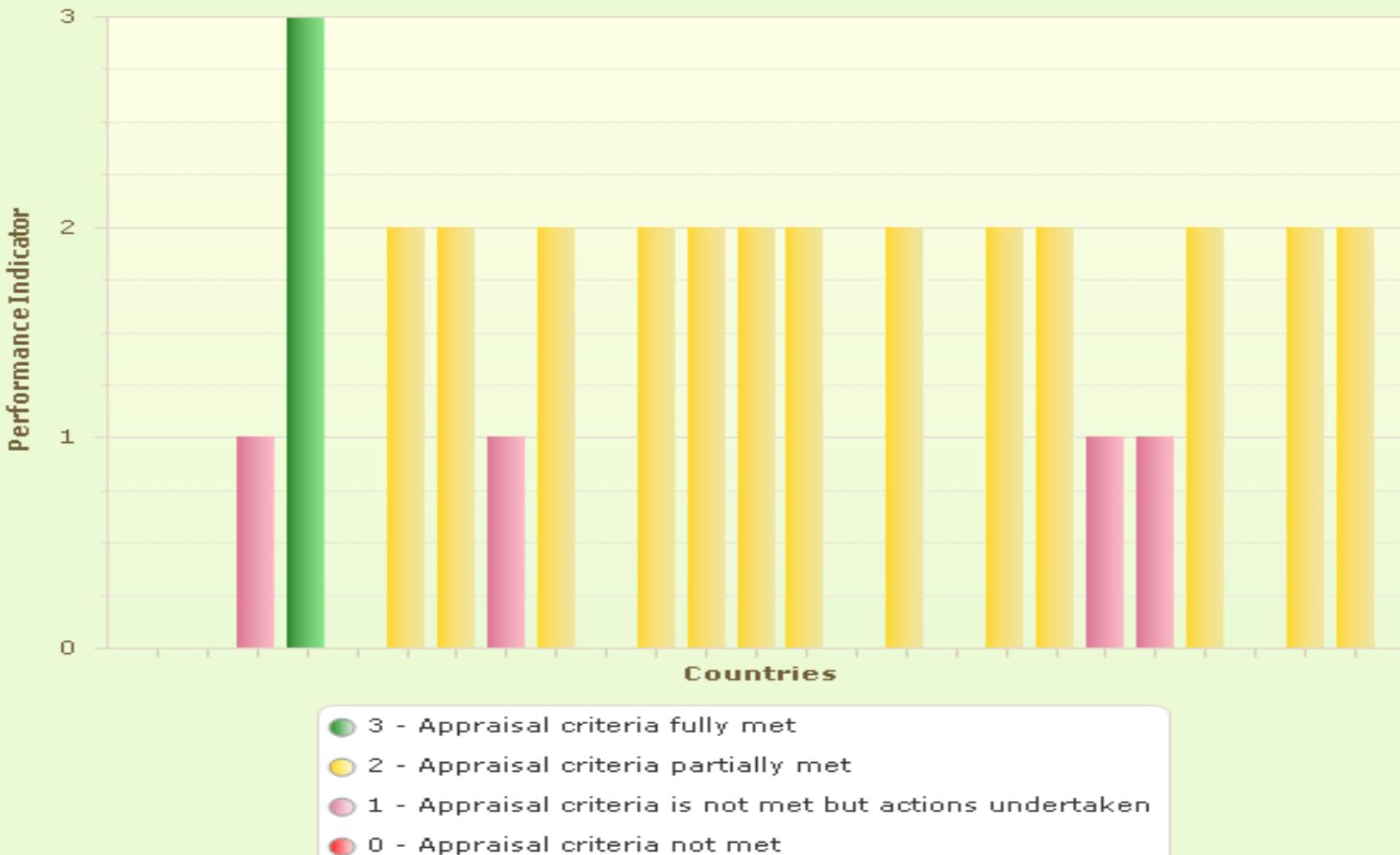


RLA 9064  
Developed 11 guides  
for authorization and  
inspection

# Inspection Program

35%

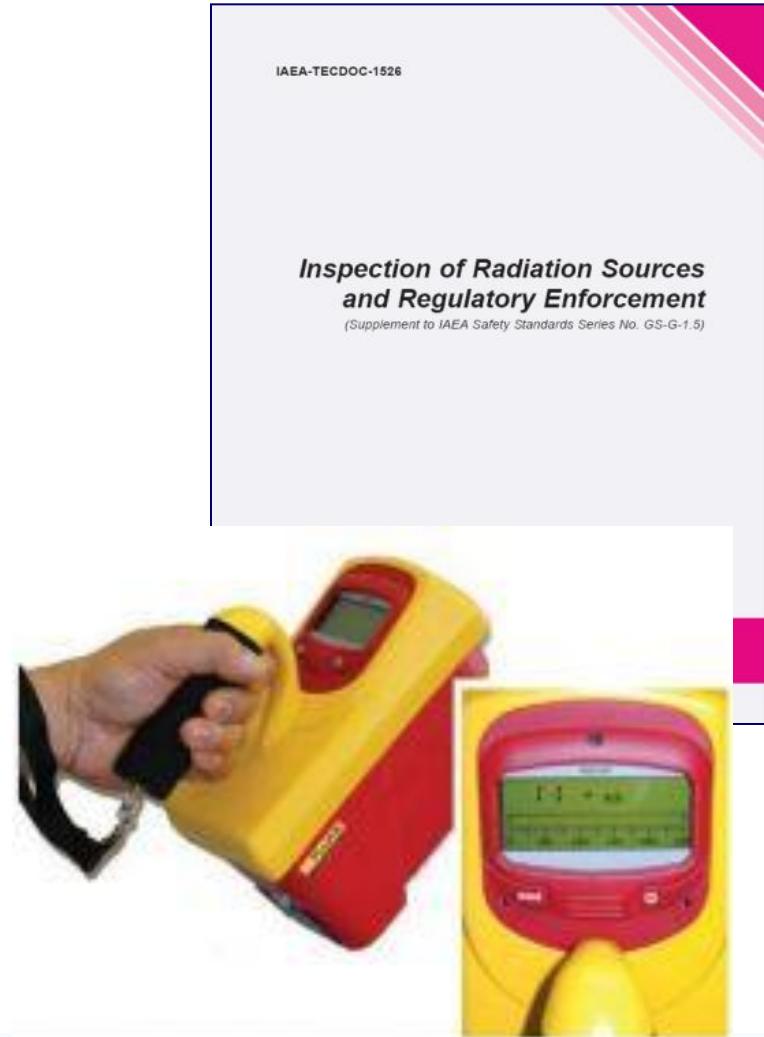
## Country Comparison By Elements in Region Latin America TSA1-11-Inspection



# Inspection Programme

35%

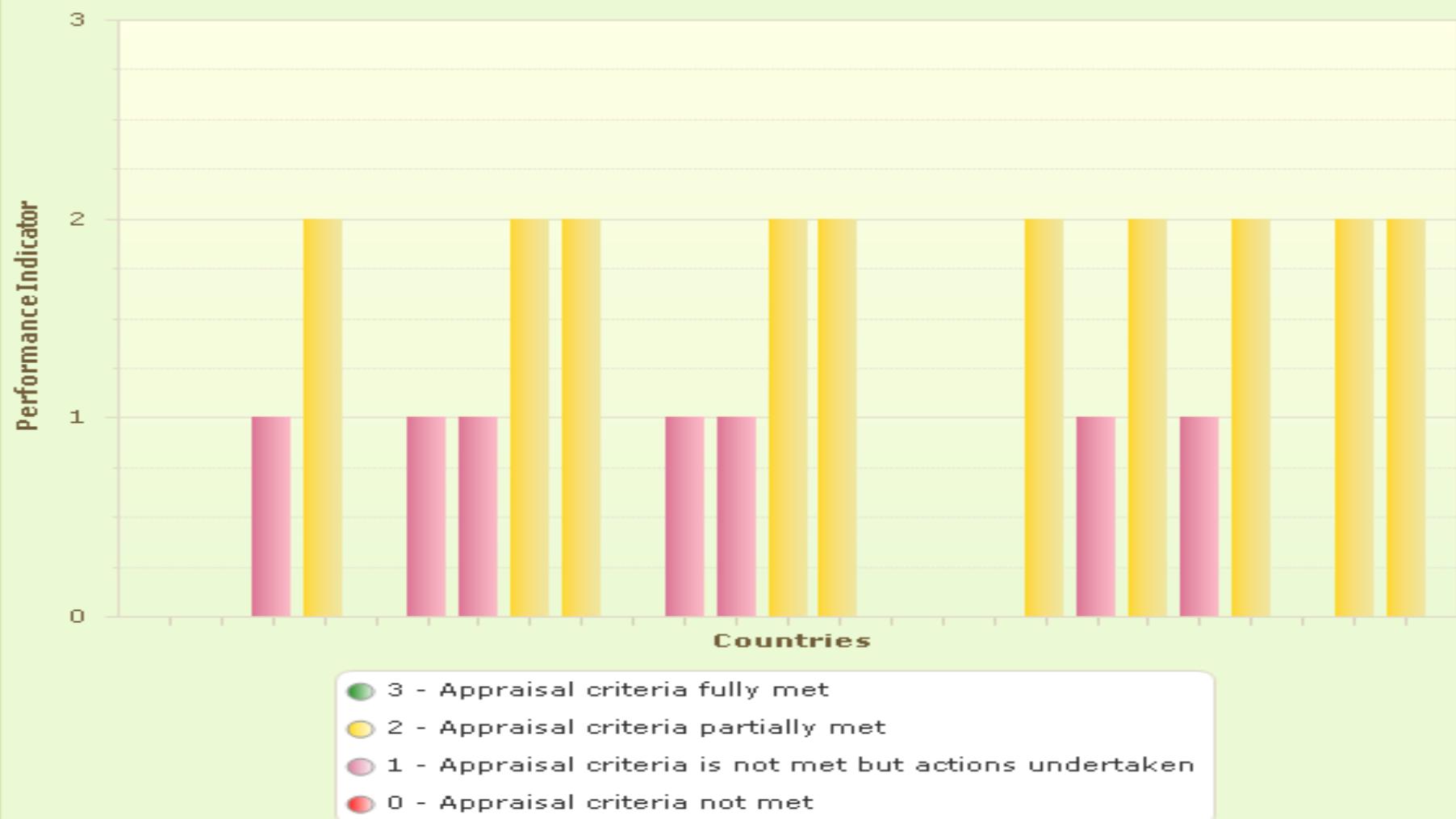
- En 10 países , los equipos de Rayos X no están cubiertos en un programa de inspección .
- Los equipos monitores de la AR para inspeccionar están sin calibración en muchos países .
- Plan de inspección no son realizados tomando en cuenta el riesgo de las fuentes



# Enforcement

60%

Country Comparison By Elements in Region Latin America  
TSA1-12-Enforcement



# Enforcement

60%

La mayoría de los países no tienen un régimen de sanciones .

8 países las autoridades reguladoras usan otras autoridades para poder hacer coerción.



# Thank You for your Attention

