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## Regulatory Control - Clinical Audit and the BSSD(key outcomes from WP 3)





#### **QuADRANT Survey on Clinical Audit**

- **Section 2** relates to the requirement for clinical audit as defined within the European
- Basic Safety Standards Directive and its enforcement through regulatory inspection





#### Questions

Answers/Results

- Analysis of the results
- Conclusions

#### Introduction



#### Section Question 2

radiological practice mandated within the European Basic Safety Standards Directive?

At individual/healthcare professional level

At hospital level

At regional/state official level

At national professional society/professional body level

At senior governmental/ministerial level

**COUNCIL DIRECTIVE 2013/59/EURATOM** 

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

s there awareness in your country of the requirement to undertake clinical audit of medical



Section	Question
2	1

- 1 country reported no awareness at any level

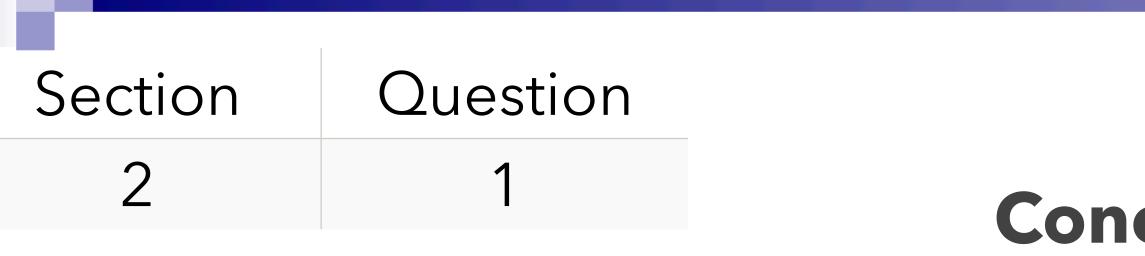
- levels
- State, hospital and individual awareness was lower

#### Results

Only 4 countries reported broad awareness at all the levels contained within the question

Broad awareness was indicated, although levels were variable and awareness was most common at national professional society (n=17 countries) and senior governmental (n=16)





Actions are required in order to increase awareness at State, hospital and individual level 

Good cooperation between regulators and professional associations is important 

audits taking into account the multidisciplinary composition of clinical audit teams

#### Conclusions

National healthcare professional education/training programs need to include training in clinical



#### Sectio

2

s there an established process of hospital/departmental inspection by the relevant national competent authority in your country?

- It was well established before the Basic Safety Standards Directive
- It has been established since the Basic Safety Standards Directive
- No it is in development
- No not in development

Don't know

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on	Question
	2



#### Section Question 2 2

- 22 countries reported this process to be in place and that this pre-dated the BSSD (2013/59/Euratom)
- In 3 countries the process was established after the BSSD
- In 3 countries the inspection process was said to be in development
- No national inspection process in existence/planned was reported in 1 country
- 2 countries did not respond

#### Results



#### Sectio

2

oes the inspection process include assessment of clinical audit?

Yes, limited to audit practice/process

Yes, including audit outcomes

□ No

Don't know

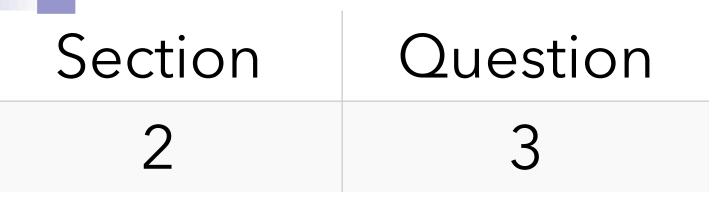
Not applicable

**COUNCIL DIRECTIVE 2013/59/EURATOM** 

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

)N	Question
	3





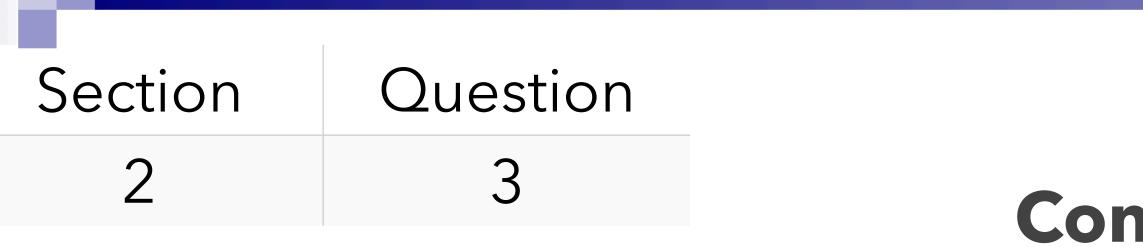
 11 countries indicated that the inspection process included the assessment of clinical audit but that this was limited to audit practice/process

In 7 countries the process was also reported to include audit outcomes

In 10 countries clinical audit assessment is not part of inspection

#### Results





In a number of countries clinical audit assessment is not part of inspection

It is recommended that clinical audit assessment be part of the inspection process

Clinical audit results should be part of the inspection assessment 

of clinical audit

#### Conclusions

• This will help to increase awareness at the hospital and individual level as well as the implementation



#### Sectio

Euratom) had on related clinical audit activity in your country?

A system of clinical audit practice and process was established as a result of the Directive Process of inspection by radiation protection/enforcement authority introduced to include assessment of clinical audit processes Clinical audit guidelines/directives developed/in development

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n	Question
	4

- hat effects (if any) has the Basic Safety Standards Directive (Council Directive 2013/59/



#### Sectio

Euratom) had on related clinical audit activity in your country?

Individual healthcare professional engagement in clinical audit mandated

guidance

**COUNCIL DIRECTIVE 2013/59/EURATOM** 

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n	Question
	4

hat effects (if any) has the Basic Safety Standards Directive (Council Directive 2013/59/

- Clinical audit activity incorporated into national hospital accreditation programmes
- Clinical audit findings/recommendations published in peer-reviewed journals/national



#### Section

had on related clinical audit activity in your country?

No change, a well-established system of clinical audit was already in place

justification and supporting audit processes)

Don't know - Other (Please specify)

**COUNCIL DIRECTIVE 2013/59/EURATOM** 

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

#### Question

4

- hat effects (if any) has the Basic Safety Standards Directive (Council Directive 2013/59/Euratom)
- □ There has been introduction of new processes/technologies or changes in practice to improve
  - audit outcomes (for example the introduction of decision support software to improve





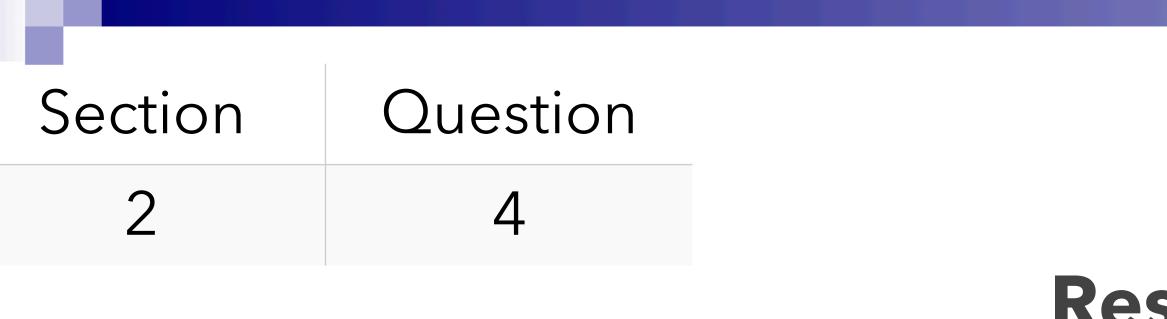


# Section Question 2

#### Results

- A well established system of clinical audit was considered already to be in place (n=9 countries)
- Clinical audit guidance development (n=13 countries)
- The inspection process to include assessment of clinical audit (n=12 countries)
- A system of clinical audit practice and process developed as a result of the Directive was described (n= 8 countries)
- Mandating of healthcare professional involvement (n=3 countries)
- Incorporation of clinical audit into hospital accreditation (n=2 countries)
- Introduction of new processes/technologies (n=3 countries)





 It is also of relevance and important to note that mandated involvement in clinical audit within departments utilizing ionising radiation procedures outside of radiology, radiotherapy and nuclear medicine only occurs in 16 countries and in private radiology/ radiotherapy/nuclear medicine providers in 17 countries

#### Results



Section	Question
2	4

the BSSD

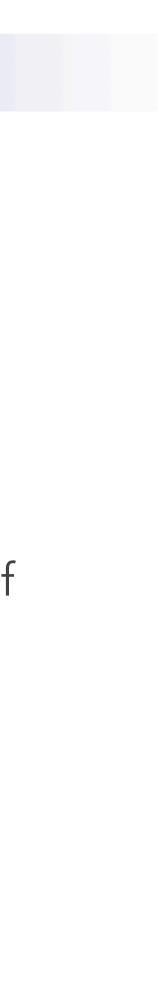
• There is no harmonised approach for the implementation of clinical audit at an European level

audit related initiatives could help a harmonised implementation of clinical audit

#### clusions

• A number of practice changes concerning clinical audit have been observed with the implementation of

• The sharing of best practices and guidance and the participation in European and international clinical



### Main Conclusions

- accordance with national procedures"
- clinical audit outcomes
- theatres...) must be provided

The BSSD provides the legal framework mandating participation in clinical audit "in

The inspection process should include clinical audit assessment as well as assessment of

Participation of the private sector and all departments undertaking ionizing imaging procedures outside of radiology/radiotherapy/nuclear medicine (orthopedic/urology/



#### Main Conclusions

- For the implementation of clinical audit there is a need to increase awareness

Education and training for all the professionals concerned should be put into place

The implementation of clinical audit has improved with the publication of the BSSD



#### Main Conclusions

However there is no European harmonised approach

organize and implement clinical audits

• It is clear that a common reference document is needed - guidelines to help countries



#### Thank you for your attention

## QUADRANT

