



World Institute for
Nuclear Security

**ROUND TABLE ON THE ROLE OF
STANDARDS FOR STRENGTHENING THE
SECURITY OF RADIOACTIVE SOURCES
USED IN MEDICAL APPLICATIONS**

22-23 January 2019

Vienna, Austria



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OPENING SESSION

Some Practicalities

- Please let me know if you want to speak or gently interrupt the speaker.
- Be here, not on the internet!
- Phones to silent, and answer calls outside the room please
- Take part, ask, share information useful to others
- If you disagree with someone, ask them why they think the way they do...before telling them why you think they are wrong
- Keep to the timetable, and be ready to start after breaks and lunch

Some Guidance

- SHARE YOUR PERSPECTIVE.
- SUPPORT IT WITH HARD EVIDENCE.
- BE OPEN TO OTHER OPINIONS.
- SEEK FOR CLARIFICATION IF NEEDED.
- IDENTIFY SOLUTIONS, NOT JUST PROBLEMS.
- SUGGEST NEXT STEPS.
- BE AMBITIOUS.

Discussing your Expectations

- With your neighbour(s), please briefly discuss what you would like to have achieved by tomorrow night?

Developing a common understanding

- ❑ What do we mean by ‘standards’?
- ❑ What is the role of standards in a highly regulated environment?
- ❑ How do we decide if a standard is needed?
- ❑ Do we have examples of standards which have impacted our work?



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SESSION 1

Security of Radioactive Sources Used in Medical Applications – A Comprehensive Review

Session 1 – Key issues

- ❑ What is the status of radioactive source security in the medical sector? Are radioactive sources used in medical applications adequately protected?
- ❑ What significant changes have occurred in the last few years? What further achievements can be expected?
- ❑ Where have we been successful? What remains to be done? What should be our priority?

Discussion on achievements and remaining challenges in the medical sector

- ❑ What are we satisfied with?
- ❑ What needs to be improved?
- ❑ What could be (innovative) suggestions for improvement?

Achievements - What are we satisfied with?

- ❑ Where have we been successful?
- ❑ What significantly contributed to these achievements?
- ❑ Have we achieved consistent level of security all along the life cycle of medical sources?

Remaining challenges in the medical sector and possible solutions

- ❑ What areas still need improvement? Are we on the way to complete these improvements (i.e. it is just a question of time) or do we need to take strong actions?
- ❑ What are your suggestions for innovative approaches that would help to enhance radioactive source security?
- ❑ Is the medical sector different from other practices? Do we need to develop a specific approach for the medical sector?

COFFEE BREAK



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SESSION 2

Strengthening the Governance Arrangements for the Security of Radioactive Sources Used in Medical Applications

Session 2 – Key issues

- ❑ What are the key elements of a security programme for radioactive sources used in medical application? Who are the main internal and external stakeholders?
- ❑ How do we demonstrate that governance arrangements are adequate? Are regulatory inspections sufficient? What could some other mechanisms be?
- ❑ How can we increase the interest and commitment of senior management to radiological security? What can we learn from other practices using radioactive sources (industry, research)?

What is security governance?

“Security governance is the means by which you control and direct your organisation’s approach to security. When done well, security governance will effectively coordinate the security activities of your organisation. It enables the flow of security information and decisions around your organisation.”

(National Cyber Security Centre, UK)

Discussion on the governance of security programmes for sources

- ❑ What are the key elements of a security programme for radioactive sources used in medical applications and who are the main internal and external stakeholders?
- ❑ What is your general feel regarding security policies? What about roles and responsibilities?
- ❑ Is security part of the overall risk management framework?
- ❑ How do we demonstrate that governance arrangements are adequate?

Sharing experiences on peer reviews and other 3rd party assessments

- ❑ What experiences in implementing peer reviews or similar mechanisms do we have?
- ❑ Is there an added-value to do peer reviews?
- ❑ Why not more peer reviews are conducted?

Accreditation and radiological security

- ❑ What experiences of accreditation do we have?
- ❑ Is it worth exploring this option as a way to strengthen radiological security?
- ❑ If yes, what actions should we take?

LUNCH



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SESSION 3

Strengthening the Security-By-Design of Devices and Associated Facilities

Session 3 – Key issues

- ❑ What are the existing initiatives for strengthening the intrinsic robustness of the devices containing radioactive sources against unauthorised removal? How efficient are these design modifications? What are their operational and financial impacts?
- ❑ What are the perspectives of the regulatory authorities and customers (end-users) on these modifications?
- ❑ What might the role of international standards (e.g. ISO standards) be for the development of security certifications for devices containing radioactive sources?
- ❑ What do we mean by security-by-design for a medical facility?

Engaging all Stakeholders - Manufacturers

- ❑ Is security by device systematically considered for any new device?
- ❑ What is the financial cost of these modifications?
- ❑ Is there an operational impact?
- ❑ What was the reaction of customers?
- ❑ What are the next steps, if any?

Engaging all Stakeholders – The regulators

- What is the perspective of the regulators on these modifications?
- Could IDD become a regulatory requirement?
- Do we have examples of regulations that include references to IDDs?

Engaging the other stakeholders

- Are we missing key stakeholders?
- What could be their role?

Developing an industry standard

- What might the role of international standards (e.g. ISO standards) be for the development of security certifications for devices containing radioactive sources?

COFFEE BREAK

Challenges and opportunities for establishing such industry standards

- ❑ What experiences of developing a standard do we have?
- ❑ Is it worth exploring this option as a way to strengthen radiological security?
- ❑ If yes, what actions should we take?

Making the case for an industry security standard for devices (and facilities) containing high activity sources

- Decide the scope of your standard.
- Prepare a justification to be submitted at an international standard organisation.
- Identify expected counter arguments against this proposal and propose answers to them.



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DAY 2

AGENDA OF DAY 2

- ❑ Reporting of group discussion on Standards
- ❑ Preliminary take aways
- ❑ Session 4 on Competences
- ❑ Developing a way forward
 - ✓ What do we want to have achieved in 3 years time?
 - ✓ How are we going to make it happen?
- ❑ Key findings of the round table and next steps (short term)



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REVIEW OF DAY 1

Session 1 - A Comprehensive Review

- ❑ Regulations usually exist but different levels of maturity. Need for harmonizing regulations (consistent requirements to support consistent security arrangements) in the world and to encourage different regulators (safety, security, medical...) to work together
- ❑ Overall, mixed feelings on achievements. A lot of room for improvement. A key issue being the engagement of senior management. Also involve conventional security staff.
- ❑ Competence of the staff is an issue. Limited security culture. Lack of beliefs in the threat, Effective and sustainable security will require improvement.
- ❑ We should not forget other security risk (voluntary modification of the settings of the treatment equipment)

Session 2 – Strengthening the Governance Arrangements

- ❑ Roles and responsibilities are usually clear. RSO (or similar) often drive the momentum. Is there a risk to rely too much on one person (resilience)? Should we promote top-down or bottom-up approaches (or both)?
- ❑ We need to better engage with senior managers. We need to speak their language (business case for security).
- ❑ Peer reviews exist in all sectors and should be more considered in our area. There is significant differences between peer reviews and audit/inspections (excellence vs. compliance). There are challenges to peer reviews (cost, availability of peers, a leading organization, etc.)
- ❑ Accreditation is common practice in the medical sector. It is peer-based. It could be a way to bring security to the attention of the senior managers. Further work is needed.

Session 3 – Security-By-Design

- ❑ IDD kits have been developed and installed in 600+ of devices. Several manufacturers have modified their design. Security by design is systematically consider from the early stages. Requires new authorization from regulators but not an issue. Limited communication or marketing on extra delay/security features.
- ❑ Limited cost and operational impact. Well accepted by customers but not really a push from them. Difficult to take credit of improvement when you cannot share blue prints and full results. Standard might be a way forward.
- ❑ Preliminary work for outreaching standard organisations. Still challenging. Need to gather more information on process and prerequisite. Experience of other sector welcome. This will be a long term effort.
- ❑ We need to develop a common understanding of “standards” and associated scope.

Making the case for an industry security standard for devices (and facilities) containing high activity sources

- Decide the scope of your standard.
- Prepare a justification to be submitted at an international standard organisation.
- Identify expected counter arguments against this proposal and propose answers to them.

Round Table Take Away

- What have you learned?
- Two actions for you
- One suggestion for your organisation
- Please take few minutes to think about it and start identifying your take aways.
- Share some of it to your neighbour and briefly discuss about it



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SESSION 4

Strengthening the Competences of Individuals with Accountabilities for the Security of Radioactive Sources

Session 4 – Key issues

- ❑ How do we identify necessary competences for the people involved in the security of radioactive sources used in medical applications?
- ❑ What education and professional development opportunities exist in the topic of radiological security? Are they generic or tailored to the medical sector?
- ❑ How do we measure the competence of the people involved in the security of radioactive sources? What might the role of certification be in demonstrating their competence?

Discussion on Security Competences

- Identify up to 3 different individuals (job positions) involved in the security of radioactive sources used in medical applications (internal and external stakeholders)
- List the knowledge, skills, and attributes you believe they should possess to effectively implement their security responsibilities
- To what extent do you believe that actual job descriptions reflect this need for competences?
- From your experience, how would you rate the (security) competence of these individuals? Do they usually possess the knowledge, skills, and attributes you identified?

Discussion on Demonstrating Competences

- How do you measure competence?
- What is the role of certification in developing and demonstrating competences?

Discussion on Professional development opportunities in radiological security

- **What education and professional development opportunities exist in the topic of radiological security?**
- **Are they generic or tailored to the medical sector?**

COFFEE BREAK



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DEVELOPING A WAY FORWARD

Developing a way forward

- For the key topics of the round table (Engagement of senior managers; Peer review and accreditation; Standards; Competences) or any other one, list up to 3 things you would like to have achieved by 2022?
- What actions need to be taken by your stakeholder group to ensure such a result?
- What support will you need from other stakeholders to make it happen?



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CONCLUSION SESSION

Review of key findings

- ❑ What have you learned?
- ❑ Where is that leading you?
- ❑ How could that enhance your contribution to the security of radioactive sources used in medical applications?
- ❑ What short term actions are you going to take personally or encourage your organization to take? (*Do you need someone in the room to help you?*)



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THANK YOU FOR YOUR PARTICIPATION!