TRAINING COURSE ON SAFETY IN BRACHYTHERAPY

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EQUIPMENT SAFETY

FROM A MANUFACTURING STANDPOINT

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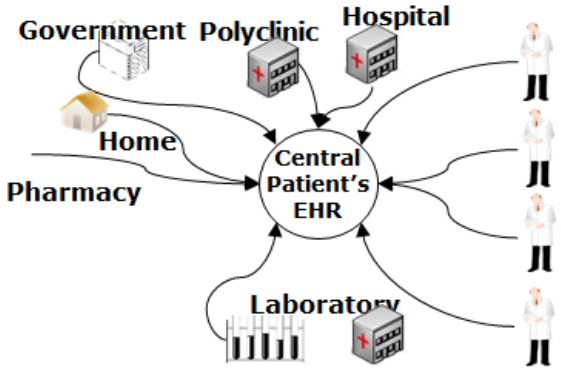
INDUSTRY SECTORS COVERED BY COCIR

COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe

COCIR covers 4 key industry sectors:

- Medical Imaging
- Radiotherapy
- Health ICT
- Electromedical

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle



COCIR EU MEMBERS

Companies

National Trade Associations

SAFETY ASPECTS

How do manufacturers adress safety aspects in brachytherapy equipment and procedures?

- Product design
- Manufacturing quality assurance
- Testing and validation
- Training and documentation
- Service and support
- Control of Source Logistics

PRODUCT DESIGN

- Specifications of a product are based on customer and commercial requirements, but also depend heavily on regulations (e.g. IEC 60601 series for electrical devices, IAEA for source containers, etc)
- Risk management and hazard analysis play a central role in the design process
- Abnormal use must be defined, usability studies are used to minimize the chance of use errors
- Safety is the most important factor in decision making regarding product features and solutions

RISK AND HAZARD ANALYSIS

- Risks are assessed and managed according to ISO 14971
- Hazard analysis is done by multifunctional teams, and registered
- Severity + Probability determine if a risk is acceptable or not
- Controls need to be defined to reduce the risk

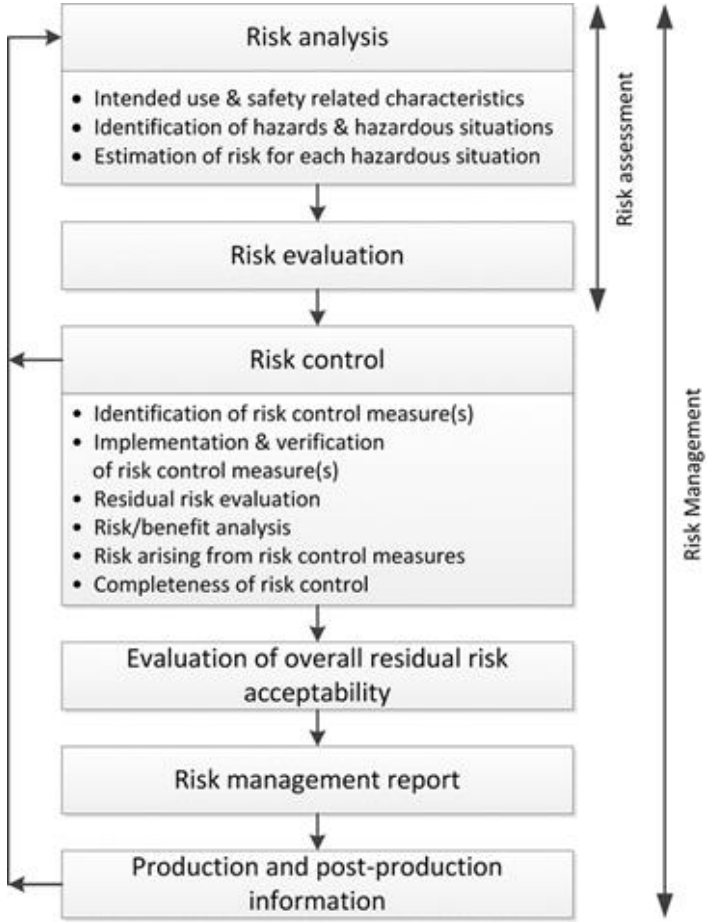
Severity	Description
Mortal injury	Injury resulting in death.
Serious injury	Injury or illness that: • Is life-threatening, • Results in permanent impairment of a body function or permanent damage to a body structure, OR • Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
Non-serious injury	Injury that: • Is non-life threatening, AND • Results in temporary impairment of a body function or temporary damage to a body structure, OR • Results in other adverse health consequences that require professional medical or surgical intervention or prescription medication to reverse or ameliorate, but do not significantly impair a body function or significantly damage a body structure.
Insignificant injury	Injury that: • Is non-life threatening, AND • Results in only slight and temporary impair of body function or slight and temporary damage of body structure (e.g. bruises, bumps) AND • Requires no professional medical or surgical intervention or prescription medication to reverse or ameliorate.

Probability	Qualitative Description
Frequent	Happens often
Probable	Likely to happen
Occasional	Can happen, but not likely
Remote	Unlikely to happen
Improbable	Highly unlikely to happen
Inconceivable	Cannot happen

RISK AND HAZARD ANALYSIS

- Controls can reduce the probability, not the severity (warnings in documentation generally do not reduce the probability)
- Risk Acceptability Criteria depend on the state of the art, standards, the disease or complication, (clinical) expert team, literature, etc

Probability \ Severity	Insignificant	Non-serious	Serious	Mortal
Frequent	Medium	High	High	High
Probable	Low	Medium	High	High
Occasional	Low	Medium	Medium	High
Remote	Low	Low	Medium	Medium
Improbable	Low	Low	Low	Medium
Inconceivable	Low	Low	Low	Low

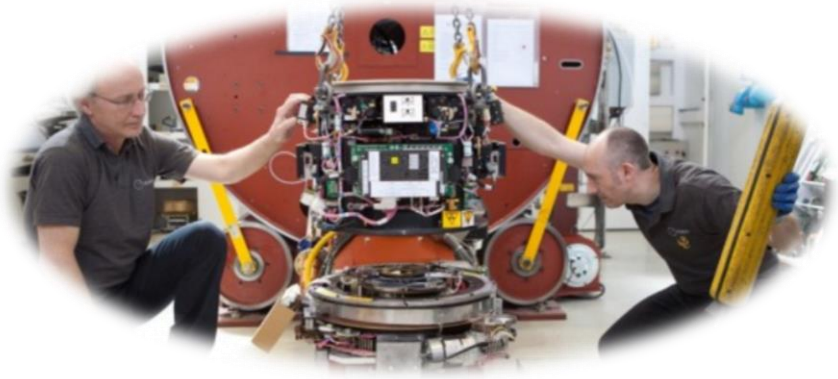


RISK AND HAZARD ANALYSIS

		Initial				Residual			
ID	**Event(s)**	**S**	**P**	**RISK**	**Risk control measure(s)**	**S**	**P**	**RISK**	**Rationale**
2347	Source gets stuck in a kinked catheter; Source movement is obstructed during treatment [Radiation hazard]	ser	occ	med	RCD2835 The system shall have an independent emergency circuitry (motor and electronics). RCD2699 The source cable drive mechanism shall be equipped with a manual emergency source retraction mechanism to retract the source manually. RCD2700 Emergency container must be available to store applicator and source in case of an emergency. RCI2703 Instructions for Use: emergency procedure RCI2704 Instructions for Use (hard copy): Emergency procedure card, provided as hard copy, to be placed in the vicinity of the control station. RCP13025 An audible alarm signal shall be generated in case of an alarm condition. RCP9812 A visual indication (red blinking color bar including 'error' message) shall be generated on the control station to indicate an alarm condition. RRCP9816 A visual alarm signal (red light, on status indicator) shall be generated in case of an alarm condition.	ser	imp	low	With the emergency procedure, if a source cannot be retracted automatically, a manual retraction is attempted. If the source cannot be manually retracted, the applicator including the source is placed into the emergency container, thereby preventing further radiation exposure. Residual risk is acceptable.

PRODUCT QUALITY ASSURANCE

- Incoming goods inspection
- Supplier validation and quality agreements
- Production process and tools validation
- Documented workinstructions for trained and qualified personnel
- Checklists and traceability (e.g. UDI)
- Regular audits



TESTING AND VALIDATION

- Testing and verification takes place at all levels and phases in the design and production process (formal testplans and reports)
- Notified bodies perform tests on the end product, e.g. against IEC 60601 for electrical safety, emission etc.
- Clinical validation of new products or major updates in cooperation with hospitals and medical professionals

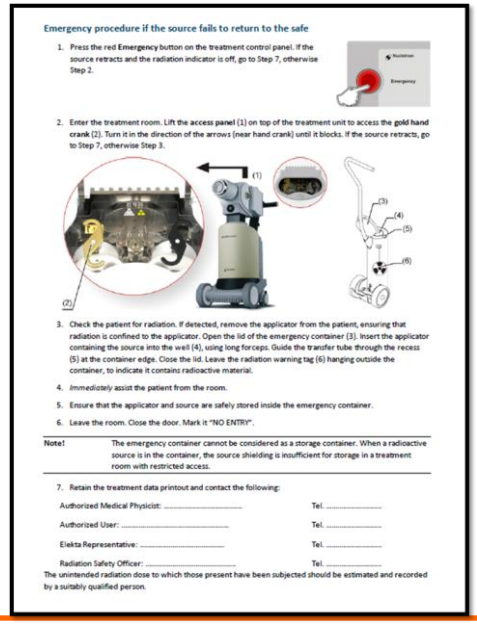
PRODUCT REGISTRATION

- Before being able to sell medical equipment, it must be registered
- Technical file must be complete
- FDA 510k, MDD, separate registrations in individual countries (China, Japan, Russia, Brazil, etc.)
- Regular inspections in the factory
- Local requirements for languages, labels, specific electrical tests

	People's Republic of China - Ministry of Information Industry Order #39
	Japan JIS C0950
	China Compulsory Certificate marked
	Russia GOST-R marked
	Brazil INMETRO marked

TRAINING AND DOCUMENTATION

- Internal: knowledgeable staff, properly qualified, procedures in place
- External: provide on-site training, e.g. on QA and emergency features of the products and corresponding procedures
- Provide proper instructions and warnings in the product documentation



Emergency procedure if the source fails to return to the safe

1. Press the red **Emergency** button on the treatment control panel. If the source retracts and the radiation indicator is off, go to Step 7, otherwise Step 2.
2. Enter the treatment room. Lift the access panel (1) on top of the treatment unit to access the **gold hand crank** (2). Turn it in the direction of the arrows (near hand crank) until it blocks. If the source retracts, go to Step 7, otherwise Step 3.
3. Check the patient for radiation. If detected, remove the applicator from the patient, ensuring that radiation is confined to the applicator. Open the lid of the emergency container (3). Insert the applicator containing the source into the well (4), using long forceps. Guide the transfer tube through the recess (5) at the container edge. Close the lid. Leave the radiation warning tag (6) hanging outside the container, to indicate it contains radioactive material.
4. *Immediately* assist the patient from the room.
5. Ensure that the applicator and source are safely stored inside the emergency container.
6. Leave the room. Close the door. Mark it "NO ENTRY".

Note! The emergency container cannot be considered as a storage container. When a radioactive source is in the container, the source shielding is insufficient for storage in a treatment room with restricted access.

7. Retain the treatment data printout and contact the following:

Authorized Medical Physicist: ..... Tel. .....

Authorized User: ..... Tel. .....

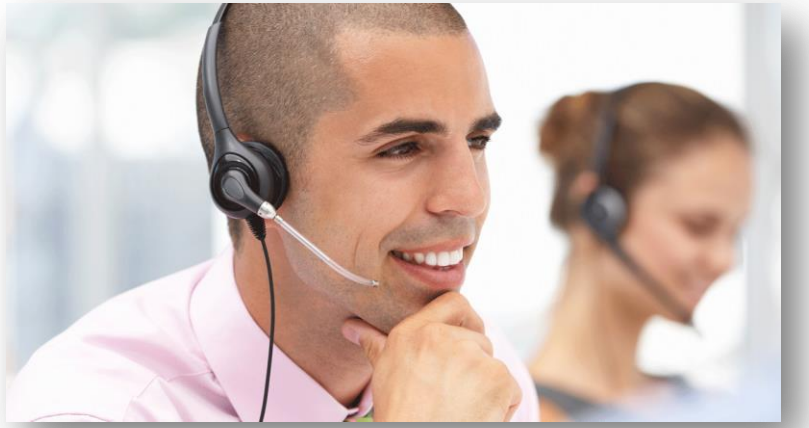
Elekta Representative: ..... Tel. .....

Radiation Safety Officer: ..... Tel. .....

The unintended radiation dose to which those present have been subjected should be estimated and recorded by a suitably qualified person.

SERVICE AND SUPPORT

- On site: installation, maintenance, updates, repairs, source exchanges, remedial work for emergency situations
- Off site: helpdesk support
- Provide user information, notifications, product bulletins
- Provide updates, fixes, improvements

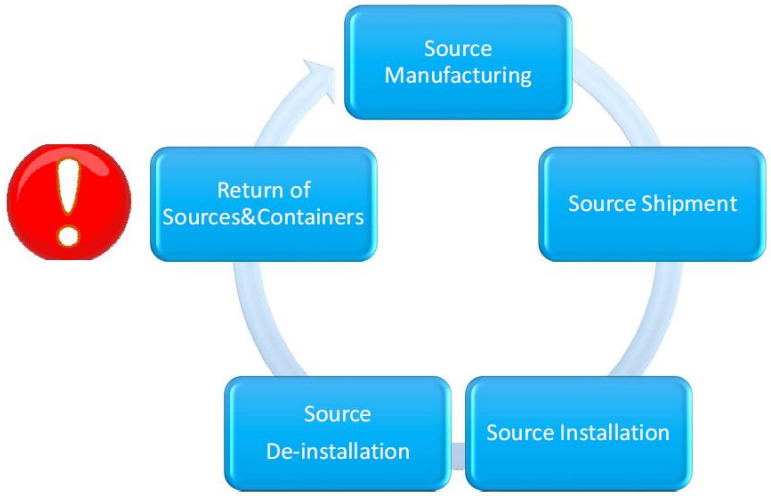


PMS - CAPA

- Post market surveillance and the complaint handling process provide feedback for issues and improvements
- Reporting to authorities (FDA, Vigilance) for safety related cases
- Root Cause Investigations lead to review and updates of the Risk management file and improvements to products
- Provide free of charge solutions within a certain time frame in case safety is affected

CONTROL OF SOURCE LOGISTICS

- Transportation of radioactive material is heavily regulated and has to comply with IAEA standards, Hass directive, IATA regulations, etc.
- Closed loop, licensing, traceability
- Risks of exposure of the public during transportation and storage
  - Theft
  - Damage (mechanical, fire, water)
  - Incorrect source position in the container
- Air transport of sources is critical for brachytherapy
  - Already many airlines do not accept radioactive material
  - Adhere to regulations, no mistakes allowed
  - Return transports are the biggest risk



HOW TO KEEP THE SNOWBALL ROLLING?

- It is not only about equipment!
- Support the international brachytherapy community through research collaboration, seminars, user meetings, funding, etc.
- Promote brachytherapy to the medical profession, health assurance agencies and patients
- Continuous product improvement
- Adapt to new regulations
- Innovation

This is only possible when brachytherapy remains safe and gets even safer!

COCIR

Sustainable Competence
in Advancing Healthcare

THANK YOU FOR YOUR ATTENTION