IAEA Training Course on Authorization and Inspection of Radiation Sources in Radiotherapy

Main elements of regulatory programme for radiation safety in radiotherapy



Module 22

EMERGENCY RESPONSE

Main elements of a regulatory programme for radiotherapy

- ❑Legislation
- ❑Regulations and guides
- ❑Authorization
- ❑Inspections
- ❑Enforcement
- ❑Emergency response

Introduction

Title of lecture:

EMERGENCY RESPONSE

This lecture will provide understanding of the role of the Regulatory Authority in case of accidents and emergencies in radiotherapy

Contents

- Types of incidents in radiotherapy
- Safety assessments
- Emergency plans
- Role of the Regulatory Authority
- Investigation of accidents
  - Objectives
  - Who should investigate
  - Radiation protection aspects of investigation
  - Accident database
  - Analysis of accidents
  - Reporting to international database

Types of incidents in radiotherapy

- Incidents that have caused, or has the potential to cause therapeutic treatment delivered to either **the wrong patient** or **the wrong tissue**, or using **the wrong pharmaceutical**, or with **a dose or dose fractionation differing** substantially from the values prescribed (underexposure or overexposure) or which may lead to undue secondary effects (overexposure)
- Any equipment failure, accident, error, mishap or other unusual occurence with the potential for causing a **patient exposure significantly different from that intended**
- **An incident causing an unusual exposure, or risk of exposure, to worker(s) or member(s) of public**

Safety assessments

- A **safety assessment** by the licensee shall be prepared and presented to the Regulatory Authority
  - For identification of accident scenarios, **arrangements of licensees with suppliers** to provide information on malfunctions should be required by the Regulatory Authority
  - **Dissemination of lessons from reported incidents and accidents** should be encouraged by the Regulatory Authority

Emergency plans

The possibility of accidents or incidents (equipment failure and human errors) must be recognized, by the help of safety assessments, and **emergency plans** put in place to deal with such events, and when appropriate, with emergency interventions.

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Emergency response- Role of the Regulatory Authority (1)

The regulatory Authority may establish **a national policy** and formal procedures for a notification, investigation and feedback mechanism for radiation incidents and accidents.

The mechanism should include the **collection and dissemination of information** among manufacturers, suppliers, maintenance companies and users.

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Emergency response- Role of the Regulatory Authority (2)

The primary responsibility for on-site emergency response lies with a licensee; **the Regulatory Authority should ensure that adequate emergency plans exist** and are capable of being operated in emergency situations -

Plans should be exercised *at intervals specified by the Regulatory Authority*

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Emergency response- Role of the Regulatory Authority (3)

The **Regulatory Authority should have plans to coordinate and implement support** to the protective actions foreseen by the emergency plans of radiotherapy licensees

- The Regulatory Authority constitutes a significant resource for radiation protection advice, and **should provide expert advice** to the government and those responsible for decision making, both in the acute phase and in the post-emergency follow-up phase

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Emergency response- Role of the Regulatory Authority (4)

- Specific **channels of communication** shall be established (telephone, fax, e-mail) for use in emergency
- **Periodic emergency drills** using realistic scenarios are essential to maintain an effective emergency response capability of the Regulatory Authority
- The Regulatory Authority should encourage **the long term followup of the patients** by the licensee (detrimental consequencies may have a long latency period)

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Investigation of accidents – Objectives

To determine

- ❖ why an accident occured
- ❖ how to prevent similar accidents
- ❖ the responsibility and liability for its consequences

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Investigation of accidents – Who should investigate?

- Minor accidents should be investigated by the **user** and the results, along with the corrective actions, reported to the Regulatory Authority
- For more serious, or potentially serious, accidents, an independent investigation by **the Regulatory Authority** (and sometimes by other governmental authorities as well) should be conducted, in addition to the investigation conducted by the **user**



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Investigation of accidents – Radiation protection aspects (1)

- Determination of the **root causes and contributing factors**
- Assessment of **consequencies** in terms of exposure and the likelyhood of exposure
  - Exposure of patient, staff (or public)
- Identification of **corrective actions**
- Deriving the **lessons to be learned**
  - Significance of findings for other radiotherapy units or departments



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Investigation of accidents – Radiation protection aspects (2)

- Recommendations for **prevention of similar accidents** in the future
  - Adjustments in the regulatory programme
  - Adjustments in the user's radiation protection programme
- **Feedback** of all findings and recommendations to relevant licensees, manufacturers,supliers etc.



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Investigation of accidents – Accident database

Users shall notify the Regulatory Authority of accidents or incidents that exceed certain specified parameters → Accident database

The Regulatory Authority should analyse such events, in particular to determine whether there are generic implications for other users



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Investigation of accidents – Analysis of accidents

- Analysis should address various aspects such as
  - Equipment design
  - Operating procedures
  - QA procedures
- Results of analysis can have implications for
  - User
  - Equipment manufacturer
  - Both user and manufacturer



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Investigation of accidents – Analysis of accidents

Follow-up actions by the Regulatory Authority when a generic problem is identified

- Notifying the details to other users who are potentially at a similar risk
- Mandatory withdrawal from service of a device at fault
- Placing of positive requirements on the manufacturer to assure corrective actions
- Modification of authorization requirements, or possible alterations to regulations



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Investigation of accidents – Reporting to international database

*The accidents and incidents, together with the lessons learned, should be reported by the Regulatory Authority to an **international database of unusual radiation events (RADEV)** maintained by the IAEA.*

Experiences accumulated in a single country may be limted, and countries should benefit from sharing information at the international level.



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Summary

- In this session we have learned that
  - The Regulatory Authority should ensure that **safety asessments** are prepared, and **emergency plans** prepared and practiced, by users, and should provide support to such activities
  - The incidents and accidents should be **investigated** by the user, and when serious, also by the Regulatory Authority, to find out the causes, mainly to prevent similar incidents or accidents in the future
  - Information on accidents should be delivered to international database (**RADEV** by the IAEA)



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Where to Get More Information

- IAEA Safety Series No 115 (BSS)
- IAEA-TECDOC-1067
- IAEA Safety Series No 9
- IAEA Safety Series No 88
- IAEA Safety Guide: Radiological Protection for Medical Exposure to Ionizing Radiation (draft, 2001)



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