Authorization and Inspection of Linear Accelerators Used in Radiotherapy
Day 5

IAEA
International Atomic Energy Agency

Agenda

- Day 5
  - Mock Inspection/Site Visit Review and Feedback
  - Machine maintenance.
  - LINAC accidents
  - Emergency procedures,
  - Handling safety violations and enforcement,

Site Visit Review

Site Visit Review

- Learning objectives
  - *During this section students will become confident using the local or IAEA inspection checklist to very compliance with safety significant regulations.*
- This review will take 120 minutes students may take breaks as needed

Site Visit Review

- Discuss identified safety issues if any and/or areas for program improvement:
  - Quality Assurance program
  - Quality Management Program
  - Written Directive Procedures
  - Treatment Plan Procedures
  - Instructor Feedback

Quiz-Questions

1. What part of the inspection was the easiest to complete?
2. What portion of the inspection was the most difficult complete?
3. What portion of the inspection was the most difficult to understand?
4. What are 3 best practices that you will implement during your next inspection?

Machine Maintenance

Machine Maintenance

- Learning objectives
  - *After this section students should understand the QA and maintenance that is done on the machine, why it is important, and steps that might be taken if it is not operating as expected.*

- This section will take 60 minutes

Machine Preventative Maintenance

- LINACs have many essential parts that can fail
- Dosimetric parameters can drift
- Machine can deviate mechanically
- Preventative maintenance - quarterly schedule

Machine Preventative Maintenance

- Clinical Engineer – services the LINAC
- Physicist – QA to return LINAC to service
- Therapists – observe and report
- Preferable to catch issues early

Machine Preventative Maintenance

- Preventative Maintenance
  - Machine voltages, wear and tear, scheduled replacement
- Routine QA
  - Flatness/symmetry, beam output, energy, mechanicals
- Machine warnings/errors
- Sounds, smells

Machine Preventative Maintenance

- Policies and Procedures
  - Routine Preventative Maintenance
  - Routine QA and Tolerances/Action Levels
  - QA after Service
  - Responsibilities and Communication for LINAC Issues

Machine Maintenance

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2 mm
	Distance indicator (ODI)	2 mm
	Safety	
	Door interlock	Functional
	Audiovisual monitor	Functional

Machine Maintenance

Frequency	Procedure	Tolerance[a]
Monthly	Dosimetry	
	x-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	x-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2 mm @ therapeutic depth
	x-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	x-ray and electron symmetry	3%
	Safety Interlocks	
	Emergency off switches	Functional
	Wedge, electron cone interlocks	Functional
	Mechanical Checks	
	Light/radiation field coincidence	2 mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 deg
	Wedge position	2 mm (or 2% change in transmission factor)
	Tray position	2 mm
	Applicator position	2 mm
	Field size indicators	2 mm
	Cross-hair centering	2 mm diameter
	Treatment couch position indicators	2 mm/1 deg
	Latching of wedges, blocking tray	Functional
	Jaw symmetry[c]	2 mm
	Field light intensity	Functional

Machine Maintenance

Frequency	Procedure	Tolerance[a]
Annual	Dosimetry	
	x-ray/electron output calibration constancy	2%
	Field size dependence of x-ray output constancy	2%
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	x-ray output constancy vs gantry angle	2%
	Electron output constancy vs gantry angle	2%
	Off-axis factor constancy vs gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturers test procedures	Functional
	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	2 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2 mm diameter
	Coincidence of radiation and mechanical isocenter	2 mm diameter
	Table top sag	2 mm
	Vertical travel of table	2 mm

Machine Maintenance

12.3 QUALITY ASSURANCE PROGRAMME FOR EQUIPMENT

12.3.4 QA program for linear accelerators

Daily tests

Procedure or item to be tested	Action level
X ray output constancy	3 %
Electron output constancy	3 %



Daily output checks and verification of flatness and symmetry can be done using different multi-detector devices.

IAEA

Review of Radiation Oncology Physics: A Handbook for Teachers and Students - 12.3.4. Slide 4

Machine Maintenance

Mechanical			
Light/radiation field coincidence[b]		2 mm or 1% on a side	
Light/radiation field coincidence[b] (asymmetric)		1 mm or 1% on a side	
Distance check device for lasers compared with front pointer		1mm	
Gantry/collimator angle indicators (@ cardinal angles) (digital only)		1.0°	
Accessory trays (i.e., port film graticle tray)		2 mm	
Jaw position indicators (symmetric)[c]		2 mm	
Jaw position indicators (asymmetric)[d]		1 mm	
Cross-hair centering (walkout)		1 mm	
Treatment couch position indicators[e]	2 mm/1°	2 mm/1°	1 mm/0.5°
Wedge placement accuracy		2 mm	
Compensator placement accuracy[f]		1 mm	
Latching of wedges, blocking tray[g]		Functional	
Localizing lasers	±2 mm	±1 mm	< ±1 mm

Quiz-Questions

1. Why is machine performance compared against baselines collected during commissioning?
2. True or False – To prevent treatment delays therapists should wait to report issues encountered during treatment until the end of the day.
3. What is the role of the physicist after LINAC service?
4. Why is routine and preventative maintenance recommended?

Quiz-Answers

1. Why is machine performance compared against baselines collected during commissioning?

    Baseline data defines TPS dosimetry

2. True or False – To prevent treatment delays therapists should wait to report issues encountered during treatment until the end of the day.

    False – Waiting could increase downtime

3. What is the role of the physicist after LINAC service?

    Release the machine for treatment

4. Why is routine and preventative maintenance recommended?

    To prevent downtime

Linear Accelerator Accidents

Linear Accelerator Accidents

- Learning objectives
  - *After this section the students should have an idea of where failures are most likely to occur and what the consequences of common failures might be.*

- This section will take 60 minutes.

Linear Accelerator Accidents

Table 1. NYSDOH LINAC medical events — Causes and contributing factors and staff involved (2001–2009).[a]

Cause and contributing factors and staff involved	Frequency of occurrence (%) (*N*=228)
Inadequate QA (Failure to follow policy and procedures)	145 (63.6%)
Documentation/communication error (includes verbal, hardcopy and data flow)	53 (23.2%)
Inadequate policy and procedures (lack of established QA protocols)	35 (15.4%)
Equipment malfunction	17 (7.5%)
Inadequate training	2 (0.9%)
Staff shortage	4 (1.8%)
Physics/dosimetry error	62 (27.2%)
Therapist error	193 (84.6%)
Radiation oncologist error	28 (12.3%)

[a]Note: Cause/Contributing Factors add up to more than 228 events and percentages add up to >100% because QA practice has redundancy. Most often, multiple failures result in an event.

Linear Accelerator Accidents

TABLE XI. Most common classifications for the possible causes for the failure shown in the IMRT fault tree analysis in Appendix E (Ref. 141).

Category	Occasions
Human failures	230
Lack of standardized procedures	99
Inadequate training	97
Inadequate communication	67
Hardware/software failure	58
Hardware	9
Software	44
Hardware or software	5
Lack of staff	37
Inadequate design specifications	32
Inadequate commissioning	18
Use of defective materials/tool/equipment	12

Linear Accelerator Accidents

TABLE 12.1. SOME EXAMPLES OF THE DIRECT CAUSES OF MISADMINISTRATIONS IN EXTERNAL BEAM RADIOTHERAPY IN THE 2000 IAEA REPORT

Cause	Number of accidents
Calculation error of exposure time or dose	15
Inadequate review of patient chart	9
Error in anatomical area to be treated	8
Error in identifying the correct patient	4
Error involving lack of or misuse of a wedge	4
Error in calibration of ^{60}Co source	3
Transcription error of prescribed dose	3
Decommissioning of teletherapy source error	2
Human error during simulation	2
Error in commissioning of the TPS[a]	2
Technologist misread the treatment time or MUs[b]	2
Malfunction of accelerator	1
Treatment unit mechanical failure	1
Accelerator control software error	1
Wrong repair followed by human error	1

Radiation Oncology – Incident Learning System

- Radiation Oncology – Incident Learning System (RO-ILS)
- 396 errors of high priority
- 44% fell into 1 of 3 categories
  - Problematic plan approved for treatment
  - Wrong shift instructions given to Therapists
  - Wrong shift performed at treatment

Radiation Oncology – Incident Learning System

- Main lessons
  - Physician errors hard to detect
  - Manual processes error prone
  - Plan checks – important but unreliable
  - Most dangerous – errors effecting whole treatment

Linear Accelerator Accidents

The Therac-25 Series of Incidents

Between June, 1985 and January, 1987 in the United States and Canada, 6 patients were massively overdosed during treatment with a linear accelerator manufactured by THE ATOMIC ENERGY CANADA LTD COMPANY [AECL]. This therapy accelerator was the THERAC-25.

No operator error was involved and it was eventually identified that two separate **MACHINE ERRORS or MALFUNCTIONS** related to the control system were the primary cause..

However the conclusions, while clearly identifying **software design errors** as a major contribution to these incidents, also identify significant contributions from:

- **failures in equipment design and design testing**
- **operational safety testing**
- **operational quality control**
- **operational procedures and departmental management**
- **lack of communication within and between radiotherapy departments**

Linear Accelerator Accidents

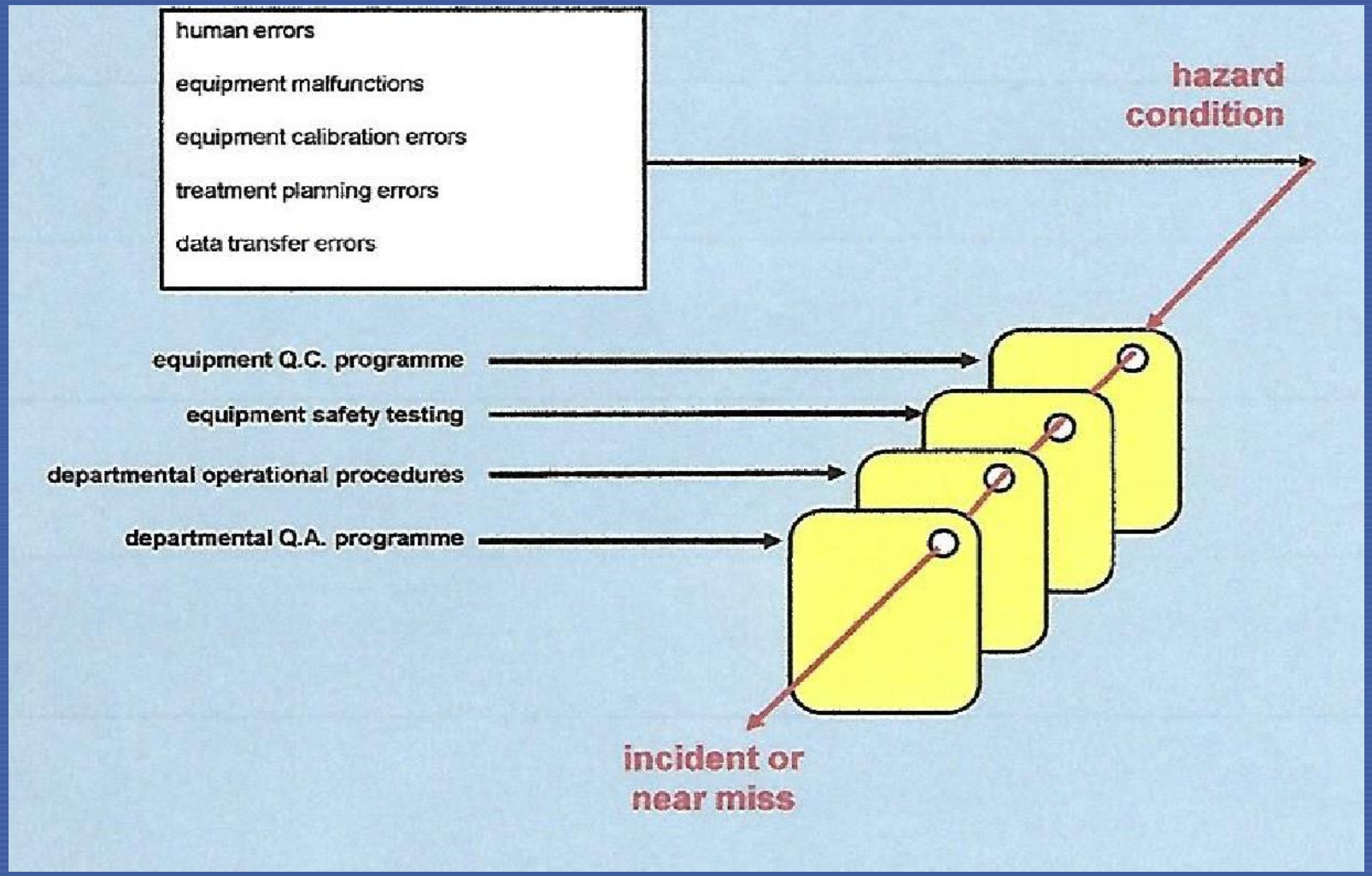
More recent incidents (perhaps not major) have involved data transfer of the radiotherapy prescriptions between different computer systems within the radiotherapy process.

Some common features appear in reports of these incidents.

- as all staff groups become more familiar with computer systems, the distinction between computer workstations for general or home use, and computers in the radiotherapy system is not always observed.
- new paradigms for the quality control and quality assurance of these computer control and imaging-based systems need to be developed

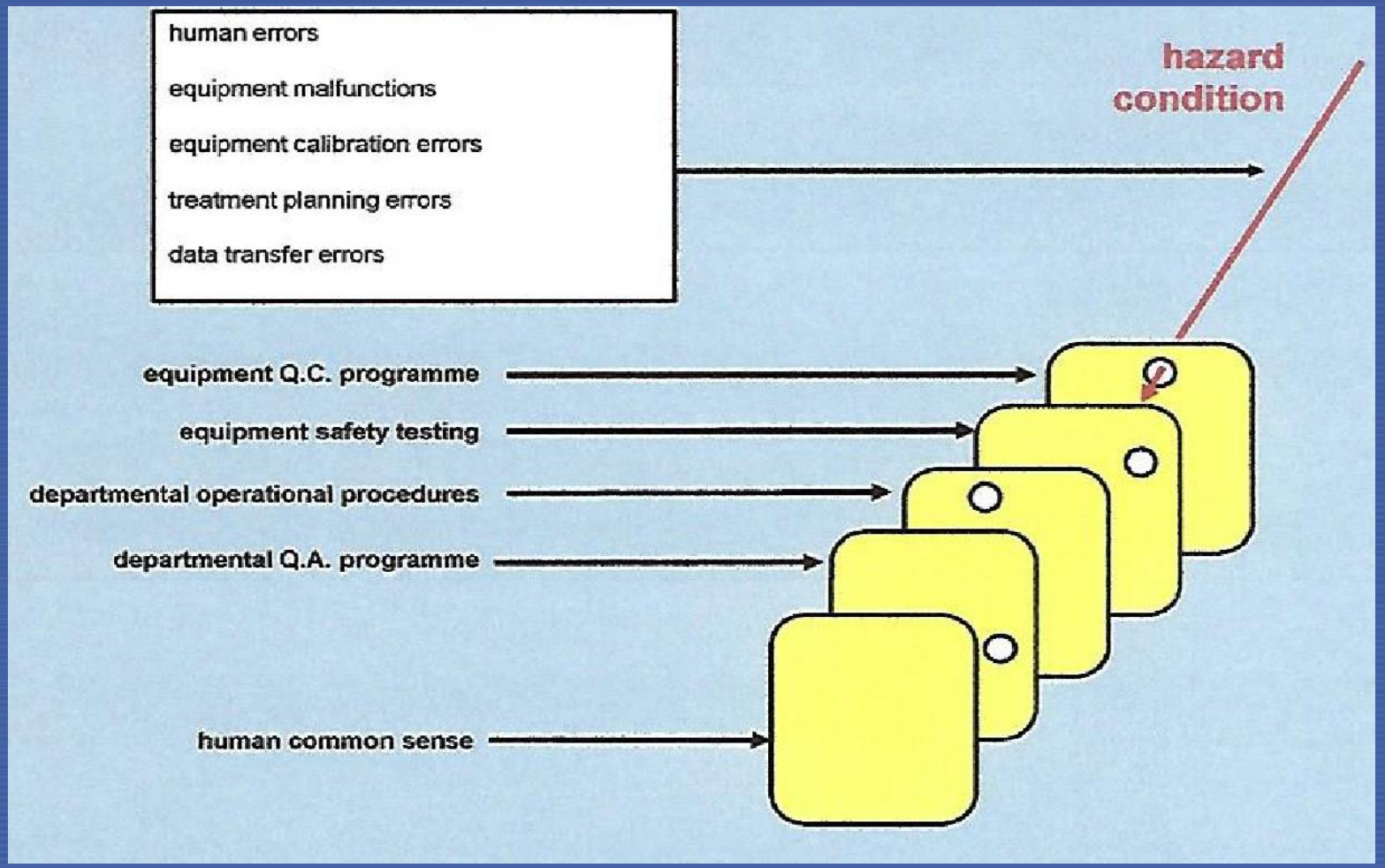
Linear Accelerator Accidents

Failure of Barriers Allows Incident



Linear Accelerator Accidents

Diversity of Barriers Prevents Incident



Linear Accelerator Accidents

- Medical Accelerator Hazards:

- Incorrect radiation dose
- Dose delivered to the wrong region
- Collision between machine and patient
- Incorrect beam energy or modality
- Other electrical and/or mechanical problems

Accident Prevention and Mitigation

- Initial Technologist Formalized Training

- General overview of the accelerator
- Operation of control console
- Treatment room area
- Emergency procedures
- Safety procedures
- Remote viewing of patients

Accident Prevention and Mitigation

- Initial Technologist Formalized Training:

- General overview of the accelerator
- Operation of control console
- Treatment room area
- Emergency procedures
- Safety procedures
- Remote viewing of patients

Risk Analysis Methods

- Prospective approach
- Review processes, failure modes
- Rating
  - Occurrence (O)
  - Severity (S)
  - Detectability (D)
- Prioritizing based on level of risk (RPN)
  - RPN = O*S*D

Risk Analysis Methods

- Indices range from 1-10
- Occurrence (O)
  - Ranges from unlikely to substantial
- Severity (S)
  - Ranges from minimal disturbance to catastrophic
- Detectability (D)
  - Very detectable to very hard to detect

Risk Analysis Methods

- Severity – consequences and how widespread
- Error in
  - Setup – impacts one patient once
  - Planning – impacts one patient for an entire course
  - Systemic – impacts all patients every treatment

Risk Analysis Methods

- Example:
  - Entering the prescription into the treatment planning system
  - O = 8, an error occurs 1/50 plans
  - S = 7, possibility for serious toxicity/underdose
  - D = 6, 1/20 prescription errors go undetected
- RPN = 8*7*6 = 336

Risk Analysis Methods

- Example:
  - Setup error during daily QA
  - O = 8, an error occurs ~10 times/year
  - S = 4, minor dosimetric error
  - D = 2, very unlikely to do undetected
- RPN = 8*4*2 = 64
- Compare to RPN = 336

Quiz-Questions

1. True or False – Manual processes are preferred as it allows trained staff to use their judgement to fit the situation.
2. Why are physician errors hard to detect, and what method was successful in doing so?
3. How must multiple barriers be designed to be effective in stopping errors?
4. What is the purpose of the prospective approach to risk analysis and the risk prioritization number?

Quiz-Answers

1. True or False – Manual processes are preferred as it allows trained staff to use their judgement to fit the situation.

False – automated processes are more reliable

2. Why are physician errors hard to detect, and what method was successful in doing so?

Other staff do not have appropriate training. Physician peer review is an effective tool.

3. How must multiple barriers be designed to be effective in stopping errors?

They must be independent.

4. What is the purpose of the prospective approach to risk analysis and the risk prioritization number?

Recognize potential failure modes before they occur and prioritize them.

Exercise 7: Medical Event Report

This exercise should take 30 minutes

Lunch

Emergency Procedures

EMERGENCY PROCEDURES

- Learning objectives
  - *After this section students should know the types of emergencies for which facilities should prepare.*

- This section will take 30 minutes.

EMERGENCY PROCEDURES

- All accelerator operators should be familiar with the location and use of the emergency STOP buttons.
- Written emergency procedures must be posted at the accelerator treatment control desk/console.
- Technologist should be familiar with all safety procedures and their location surrounding the medical accelerator.

EMERGENCY PROCEDURES

- A licensee or registrant shall develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
- The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

EMERGENCY PROCEDURES

- Types of emergencies and abnormal occurrences
  - Patient health emergency
  - Power failure
  - Fire/Disaster
  - Threat
  - Equipment failure

Quiz-Questions

1. True or False – It is acceptable to have the emergency procedures only filed electronically so long as all staff have been trained in them

2. Whose phone numbers must be on the emergency procedures?

Quiz-Answers

1. True or False – It is acceptable to have the emergency procedures only filed electronically so long as all staff have been trained in them

   False – Must be posted

2. Whose phone numbers must be on the emergency procedures?

   Authorized users, authorized medical physicist, and radiation safety officer

Handling Safety Violations and Enforcement

Safety Violations and Enforcement

- Learning objectives
  - *After this section the students should know the types of violations, types of sanctions, and the expected response for each.*

- This section will take 60 minutes.

Safety Violations and Enforcement

- Types of violations:
  - Against regulatory (regulation) requirements
  - Against License and/or Registry Conditions
  - Failure to follow procedures:
    - operating procedures;
    - emergency procedures, etc.
  - Medical event, as defined in regulation.
-

Enforcement Policy

- Should be developed to support the regulatory agency's overall safety mission in protecting the public and the environment.
- Enforcement action should be used as a deterrent to emphasize the importance of compliance with regulatory requirements.
- Encourage prompt identification and prompt, comprehensive correction of violations.

Enforcement Policy

NRC Enforcement Policy is published as NUREG-1600, “General Statement of Policy and Procedure…”

Three primary enforcement sanctions:

1. Notices of Violation (NOV);
2. Civil Penalties (CP); and
3. Orders

Enforcement Sanctions

- A NOV identifies a requirement and how it was violated.
- A CP is a monetary fine issued under the authority of the regulatory body as set forth by the law or Act of the government.
- Orders modify, suspend, or revoke licenses or require specific actions by licensees or persons.

Response to a NOV

- A response to violations should include for each violation:
  - The reason for the violation;
  - The corrective steps that have been taken and the results achieved;
  - The corrective steps that will be taken to avoid future violations; and
  - The date full compliance will be achieved.

Quiz-Questions

1. True or False – Violations only pertain to regulations.

2. What is the purpose of enforcement policy?

3. What is the expected response to a notice of violation?

Quiz-Answers

1. True or False – Violations only pertain to regulations.

   False

2. What is the purpose of enforcement policy?

   Safety

3. What is the expected response to a notice of violation?

   Corrective action

Summary : Questions and Answers

Award Course Certificates

Closing Remarks