IAEA Tecdocs for inspecting justification and optimization

6-8 November 2018, MedInspector, Stockholm

Ritva Bly

Content

- Descriptive and prescriptive inspections
- IAEA-TECDOC-1526
- New IAEA TECDOC: Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources in Use and Storage and of Associated Facilities
  - A form for inspecting nuclear medicine

Descriptive and prescriptive inspectins

Descriptive

- List of detailed questions
- Y/N answers
- Easy to ask – some relevant information may not be available if there is not a suitable question
- Difficult to apply graded approach
- Easy to repeat in a similar way

Prescriptive

- Open questions (why?, what?) and requests to describe
- Understanding of the practice to be inspected needed – an inspection form or a check list supports the inspector
- Easy to apply graded approach
- Inspection depended of the inspection skills of the inspector

IAEA-TECDOC-1526

9. UNSEALED RADIATION SOURCES

	Yes	No
Radionuclides, chemical form, maximum activities at any time, and uses as authorized and confirmed by the source utilization log book?		
Operator obtains prepared doses from an authorized radio- pharmaceutical supplier?		
Supplier's name, address		
Operator obtains and uses $^{99}Mo/^{99m}Tc$ generators?		
^{99}Mo breakthrough tests performed as required?		
Comments:		

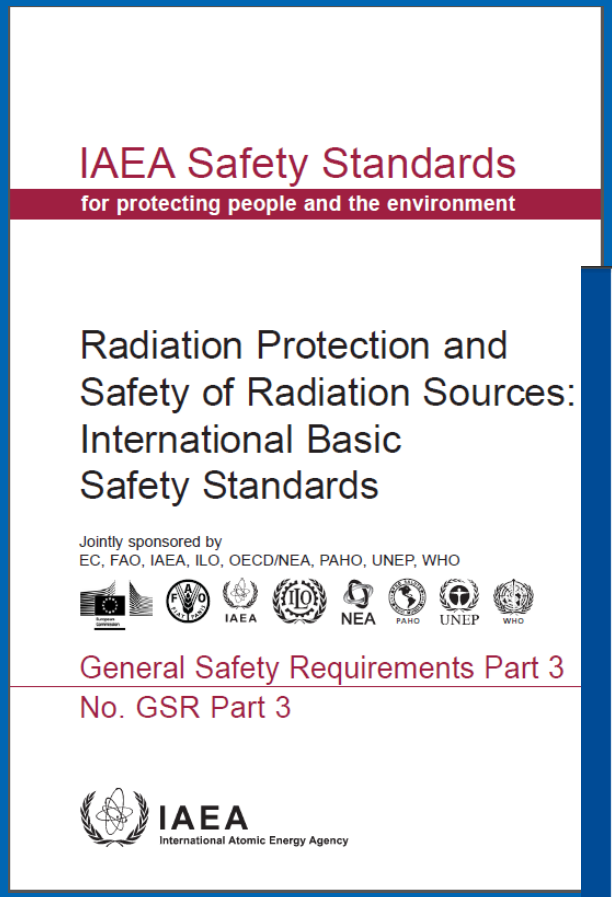
10. RECEIPT AND TRANSFER OF RADIATION SOURCES

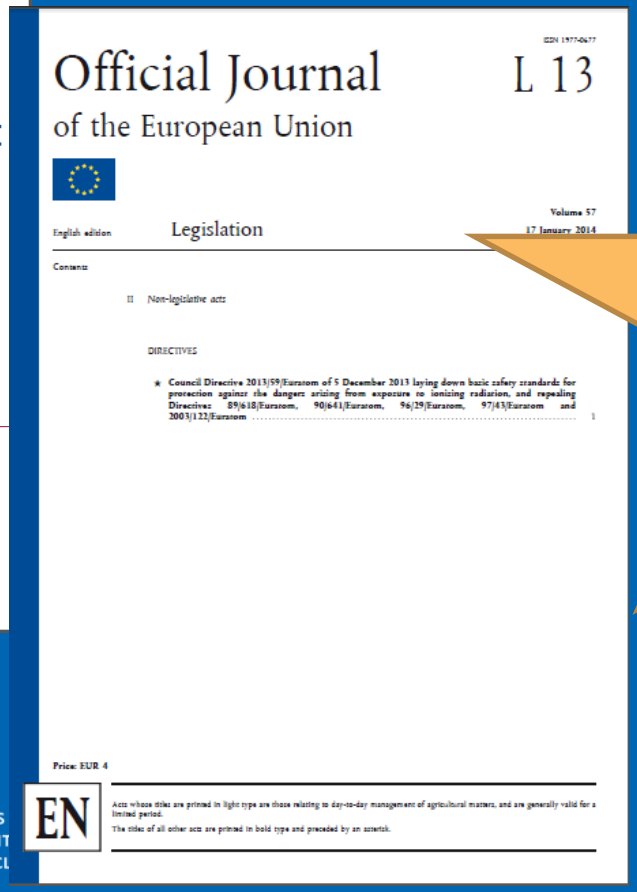
	Yes	No
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential radioactive contamination before opening?		
Records of packaging surveys, source receipt and transfer maintained?		
Comments:		

11. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL
Radiological surveys; leak tests; source existence checks; handling of radioactive materials; records; contamination control [BSS - Section I.38]

	Yes	No
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Area exposure rate surveys are performed at appropriate intervals?		
Surveys for removable contamination, including fume cupboards, conducted as required?		
Records of calibrations, contamination surveys, etc. maintained?		

What is missing in the IAEA-TECDOC-1526?





Medical use of radiation:
-Medical exposure
-Occupational exposure
-Public exposure

Aspects of patient protection are missing

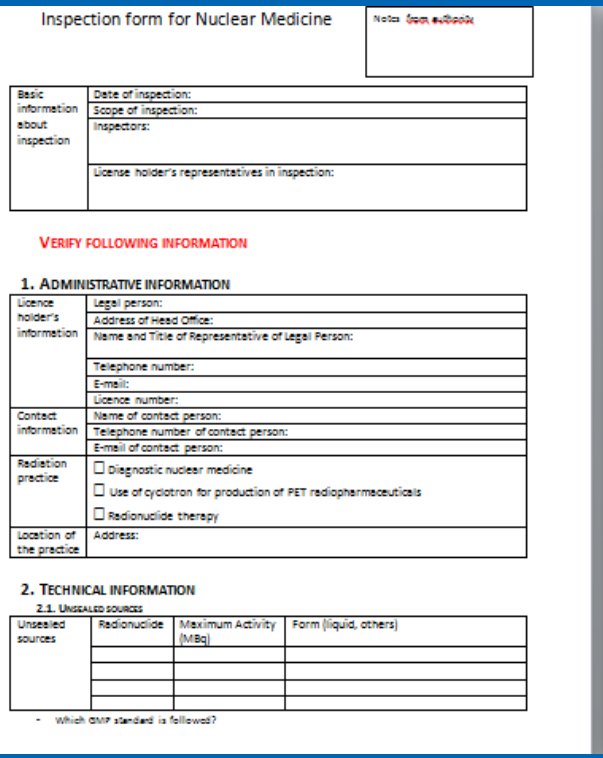
stuk
SÄTEILYTURVAKESKUS
STRÅLSÄKERHETSCENT
RADIATION AND NUCL

Where are risks in the NM?

1. Medical exposure
   - Comparison of doses to other imaging procedures
   - NM therapy procedures – consequences if the dose is too low or too high compared to the prescription
   - Justification and optimization
   - Carers and comforters
2. Occupational exposure
   - Comparison to dose limits
3. Public exposure
   - Comparison to dose limits

A new IAEA form for NM inspection

- Comparison to the information given in the license application
- Special focus on the patient protection in this presentation



Inspection form for Nuclear Medicine

Notes from authority

Basic information about inspection	Date of inspection:
	Scope of inspection:
	Inspectors:
	License holder's representatives in inspection:

VERIFY FOLLOWING INFORMATION

1. ADMINISTRATIVE INFORMATION

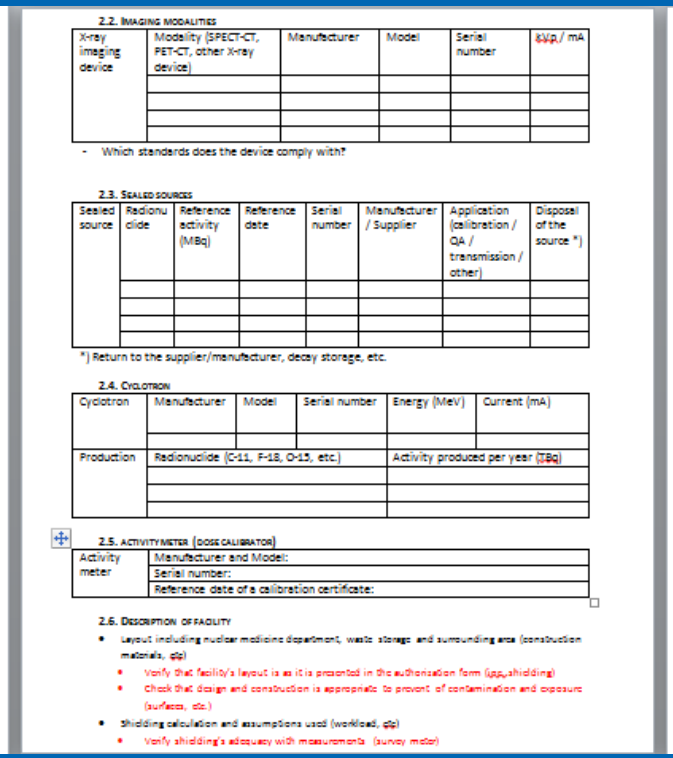
Licence holder's information	Legal person:
	Address of Head Office:
	Name and Title of Representative of Legal Person:
	Telephone number:
	E-mail:
	Licence number:
Contact information	Name of contact person:
	Telephone number of contact person:
	E-mail of contact person:
Radiation practice	☐ Diagnostic nuclear medicine ☐ Use of cyclotron for production of PET radiopharmaceuticals ☐ Radionuclide therapy
Location of the practice	Address:

2. TECHNICAL INFORMATION

2.1. UNSEALED SOURCES

Unsealed sources	Radionuclide	Maximum Activity (MBq)	Form (liquid, others)

- Which GMP standard is followed?



2.2. IMAGING MODALITIES

X-ray imaging device	Modality (SPECT-CT, PET-CT, other X-ray device)	Manufacturer	Model	Serial number	kVp / mA

- Which standards does the device comply with?

2.3. SEALED SOURCES

Sealed source	Radionuclide	Reference activity (MBq)	Reference date	Serial number	Manufacturer / Supplier	Application (calibration / QA / transmission / other)	Disposal of the source *)

*) Return to the supplier/manufacturer, decay storage, etc.

2.4. CYCLOTRON

Cyclotron	Manufacturer	Model	Serial number	Energy (MeV)	Current (mA)
Production	Radionuclide (C-11, F-18, O-15, etc.)			Activity produced per year (TBq)	

2.5. ACTIVITY METER (DOSE CALIBRATOR)

Activity meter	Manufacturer and Model:
	Serial number:
	Reference date of a calibration certificate:

2.6. DESCRIPTION OF FACILITY

- Layout including nuclear medicine department, waste storage and surrounding area (construction materials, etc)
  - Verify that facility's layout is as it is presented in the authorisation form (e.g. shielding)
  - Check that design and construction is appropriate to prevent of contamination and exposure (surfaces, etc.)
- Shielding calculation and assumptions used (workload, etc)
  - Verify shielding's adequacy with measurements (survey meter)
  - Verify that assumptions used for shielding calculations are still valid
- Features to prevent contamination / facilitate easy decontamination
  - Verify that surfaces are appropriate
- Air pressure differentials and directions of air flow
  - Check air pressure differentials contain the activity in controlled area (no release of activity to for example to corridors)
- Release points for liquid and gaseous waste discharges
  - Check that all gaseous discharges are monitored and monitors are calibrated
  -
- Safety features (location, technical description, etc.)
  - Check and verify
- Classification of areas
  - Check the contamination
  - Check warning signs

2.7. MONITORING EQUIPMENT

- Technical information about monitoring equipment (survey meters, contamination meters, stack (chimney) monitors for cyclotrons, etc.)
  - Check the equipment (working condition and calibration)
  - Check the bookkeeping of the measurements results
- Describe all the monitoring systems

3. OCCUPATIONAL EXPOSURE

3.1. RADIATION PROTECTION OFFICER
Name, education, training and experience, contact details

3.2. QUALIFIED EXPERT
Name, education, training and experience, contact details

3.3. WORKERS
Name, education, training, retraining, personal dosimetry, health surveillance
- Check unexpected doses of workers

3.4. SAFETY ASSESSMENT OF POSSIBLE RADIATION RISKS FROM OCCUPATIONAL EXPOSURE
- Estimated doses to workers from planned and potential events
- Check that the estimated doses
- Estimated probability of occurrence and magnitude of the events
  - Check (documents, etc.)

3.5. RADIATION PROTECTION PROGRAMME
- Description of organizational system including responsibilities for radiation safety (description of integrated management system)
- List of procedures and local rules
  - Check (documents, etc.)
-

4. PUBLIC EXPOSURE

4.1. RADIOACTIVE WASTE MANAGEMENT

Patient protection 1/5

RESPONSIBILITIES

Check and verifiy:

- Clinical responsibility (name of the nuclear medicine specialist, qualification of this person)
- Medical physicist / medical physics service (name)
  - BSSD: The use of Medical physics expert shall be involved (or closely involved)
  - Art 83 2. Member States shall ensure that depending on the medical radiological practice, the medical physics expert takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following….

Patient protection 2/5

JUSTIFICATION

- Are diagnostic examinations /treatments based on prescription?
  - Make a point check
- How the patient is verified that she is not pregnant?
  - Verify by asking the justification and documentation, check, signs, brochure, procedures, etc…
- Justification for pregnant persons / children
  - Check criteria, verify information
- Procedure for the patient identification (inc. QA)
  - Ask and observe
- Arrangements to ensure justification (examinations and treatments are based on prescriptions)

Patient protection 3/5

OPTIMIZATION

- List of procedures for most common diagnostic examinations and treatments
  - Ask and observe documentation
  - Pay attention to the dosage of the activity and therapy dose planning
- Patient records (radionuclide, radiopharmaceutical, activity, type of examination/treatment)
  - Make a point check
- Use of diagnostic reference levels (DRLs)
  - Check information

Patient protection 4a/5

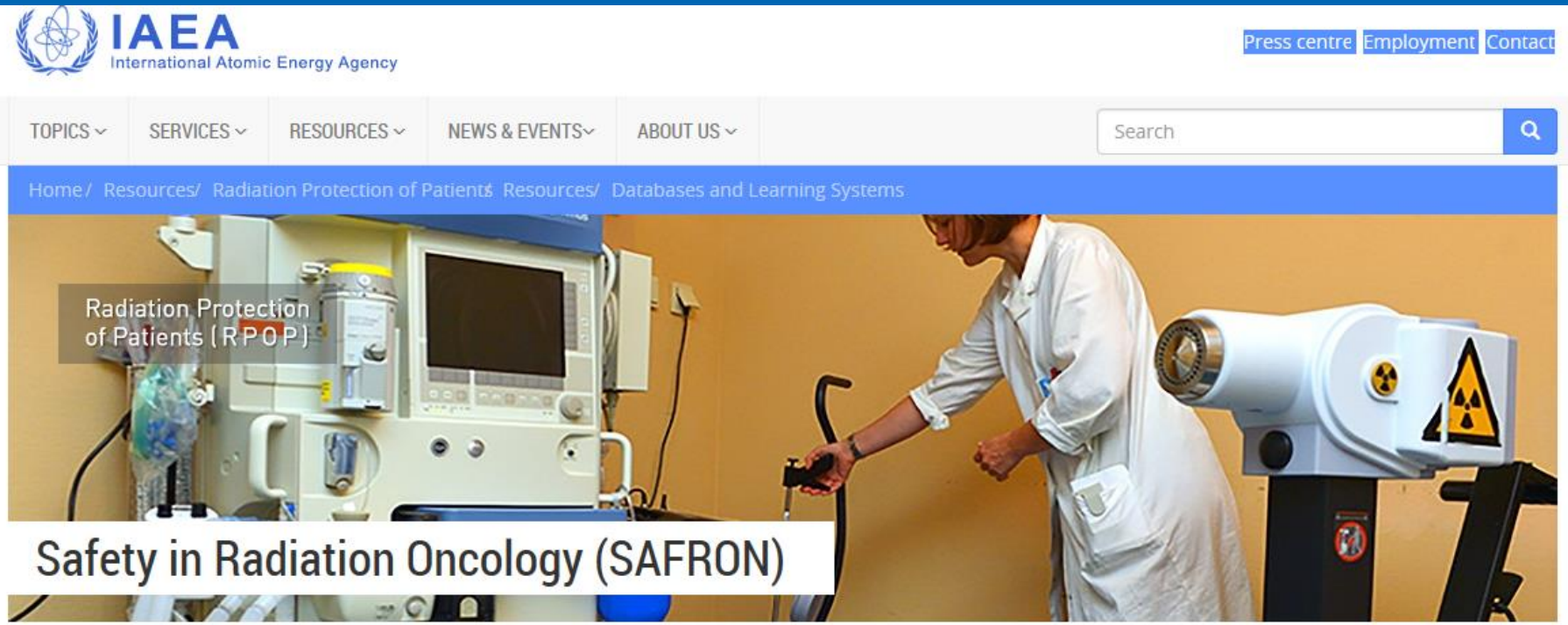
QUALITY ASSURANCE 1/2

- Technical Quality Control (QC)
  - Check results from QC (point check)
  1. Acceptance testing (responsibilities, criteria for tests)
  2. Quality Control programme
     - Description of the periodical test:
     - Tools needed to perform the test
     - How to perform the test
     - Frequency of the test
     - Performing person / a responsible person
     - Action levels and actions to be taken
     - Recording of the test results
       - Check results
  3. Description of maintenance
  4. Independent audit

Patient protection 4b/5

QUALITY ASSURANCE 2/2

- Other Quality Assurance
  - Reporting and learning systems
  - Self-assessment



Patient protection 5/5

Release of patients after radionuclide therapy and instructions for patient

- Check information

Procedures for comforters and careers

- Check information (brochure, etc…)
- Dose constraints

Specific procedures for pregnant and breast feeding women

- Check information (brochure, etc…)

Two approaches in the future

The TECDOC-1526 will be still available in the future

The new TECDOC is in the finalization at the IAEA