Regulatory framework and inspections in France

Related to nuclear medicine

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Nadège FAYARD
Autorité de sûreté nucléaire (ASN)
Ionising Radiation and Health Department

Transposition of the BSS Regulatory framework

3 implementing decrees of June, the 4th, transposing BSSD (published on 5 June 2018)

→ Modify regulatory parts of the Labour, Public Health, Environment and Defence Codes (various ministries)

→ For nuclear medicine : Labour and Public health codes.

Transposition of the BSS Regulatory framework

Major Changes: Public and Patient Protection

→BSSD transposition and creation of additional tools for reinforcing the effectiveness of the oversight of nuclear activities

–Reinforcement of the use of the justification and optimisation principles (introduction of "dose constraint" and "reference level" notions).

- → *Recommendations on dose constraint for carers and comforters for patient after iodine-131 therapy / no constraint in other cases*
- → *New diagnosis reference levels: total activity / activity per kg / PET-CT levels (CTDI [mGy] – DLP [mGy.cm])*

–Creation of an intermediate administrative system "Registration" for small-scale nuclear activities for introducing the graded approach.

- → *biological analysis using radionuclides*

–Extension of the checks carried out by the external organisations approved by ASN (collective protection of workers, maintenance and quality control of medical devices, doses to patients during medical diagnosis examination).

–The regulatory system concerning the radiation protection of patients is updated (medical procedures justification, health professionals training and quality assurance).

Inspection focuses in nuclear medicine

- ***Occupational radiation protection***
- ***Patient radiation protection (including justification, optimisation, quality management)***
- ***Environment protection (sources, solid and liquid wastes)***

- Main inspection areas:

- staffing levels, qualifications and training
- radioactive source management
- radiation protection program:
  - duties of the radiation protection officer
  - risk assessment
  - occupational exposure monitoring for the different categories of workers
- medical physics program:
  - QA and QC
  - justification and optimisation
- Procedures for radioactive waste management

Inspections in nuclear medicine – Skills of inspectors

Inspectors: ~ 300 inspectors for radiation protection and nuclear safety

- engineers (+++), health professionals (~ 10), pharmacists (12) ou physicians (6) or health sciences engineers (~ 5) of Ministry of Health

Training:

- General training in radiation protection (occupational, patient, environment…): 3 – 4 weeks
- Specific training on medical activities: 1 week and 1 week in a hospital
- Others (events…)

Each inspector conducts at least 14 inspections a year (as a leader), in medical or industry

1 inspection= 2 inspectors, or more :

– 2 from regional department of ASN
– or 1 inspector from department and 1 from direction

± 1 expert or 1 inspector not yet experienced

Inspection method and frequency - 1

➢ *To verify the compliance of licensees with legislation and conditions specified in authorization*

- National level defines guidance, priorities and frequencies of inspections
- Inspection tools are developed by ASN national level (inspection guidance, technical documents) and by local offices (inspection check-lists)
- At least 2 weeks before the inspection day: a formal ASN letter is sent to the licensee to announce the inspection.

- The inspection is conducted by two inspectors:
  - opening meeting with the hospital management
  - interviews with the management and relevant staff
  - checking of procedures and registration documents
  - visual inspection of the nuclear medicine department and the equipments
  - exit meeting: with the licencee; summary of the findings, details about the requested corrective actions.

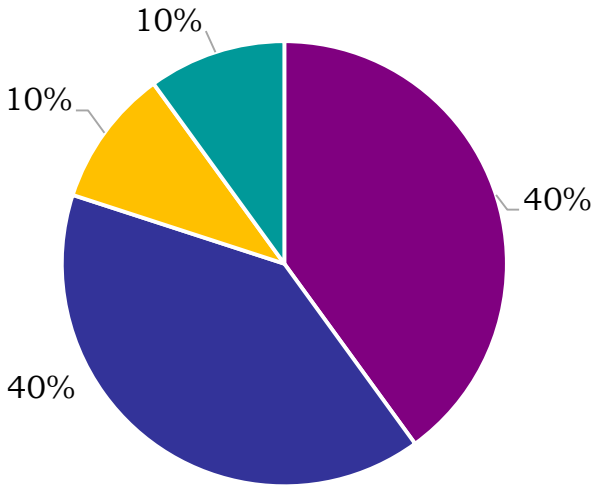
Inspection method and frequency - 2

- Inspection outputs: inspection follow-up letter sent to the head of the facility and to the employer within the 3 weeks after the inspection and published on ASN website (https://www.asn.fr/Controler/Actualites-du-controle/Lettres-de-suite-d-inspection-dans-le-domaine-medical)
- The licensee's answer is expected within two months
- Follow-up of the corrective actions by the leader inspector.
- In case of significant non-compliance, ASN can use its enforcement powers (authorisation suspension…).

Inspection method and frequency - 4

236 nuclear medicine units:

- **40% in public hospitals**
- **40% private centers**
- **10% cancer centers**
- **10% others (Army…)**



2017:

- 158 shielded rooms in 46 NM units
- 6400 patients with iodine-131 in shielded room
- 6600 patients treated without hospitalisation (131-I, 153-Sm…)

Inspection method and frequency - 3

Frequency of inspections

Since 2013, inspections frequencies defined according to a graded approach:

- Every 5 years for NM department performing only diagnostic procedures;
- Every 3 years for units having therapeutic activities (including or not iodine therapy in shielded rooms)

In 2019 → 4 years for units performing diagnostic procedures and out-patient iodine therapy *(~ 70 inspections)*

	2012	2013	2014	2015	2016	2017	2018
Nb of inspections	86	67	63	53	67	62	80

Scope of Inspection in nuclear medicine – 1

Since 2018 : systematic items of control (in French "PIC"):

- ***To adapt the control to the activities associated radiation risk***

  1. To check a limited number of common core items: 17 standard questions/grid of answers/national indicator

  =>To get a national overview of the radiation protection fundamentals in NM dpts

  2. To allow deeper investigations on site-specific relevant items, identified by the inspector

  => To better implement a graded approach

  3. To get national statistics

17 items

- 6 → occupational exposure
- 3 → external technical controls / verifications and follow-up
- 2 → patients radioprotection (medical physic, information of patient after therapy)
- 1 → quality control
- 1 → significant events (procedures…)
- 4 → waste

Scope of Inspection in nuclear medicine - 2

Since 2018 : mandatory items of control:

2 items on patient radiation protection

1- Medical physics program describing

- Identify the medical physics expert position: employee of the care center or a service provider?
- Quantify the time of the medical physics expert dedicated for the NM department, according to the current practices in the NM unit (therapy or not, nb of cameras…)
- Quality controls procedures
- Collect and analysis of doses and activities delivered to the patients and comparison to the national diagnostic reference levels (DRL) defined by ministerial order
- Follow-up of these analysis (optimization of parameters of CT-Scan, of radiopharmaceuticals…)

Scope of Inspection in nuclear medicine - 3

Since 2018 : mandatory items of control:

2 items on patient radiation protection

2 – (written) Information to the patient after therapy or diagnostic procedure

- Order of Ministry of health (21 janvier 2004)
  - For all NM procedures: information about ionizing radiations risks and information to limit relatives exposure
  - Written information before therapeutic procedure (activity, radiopharmaceutical; number of days with limited contacts, drink…)

- Recommendations of the French society of nuclear medicine (SFMN)
  - Restrictions on contacts and travels + hygiene measures + drink…

→ What information is given to patient to limit exposure for people in contact with patient released from the NM unit (hygiene, limited contacts, with children and pregnant women…)

Scope of Inspection in nuclear medicine - 4

Since 2018 : mandatory items of control:

1 items on quality control

External quality control :

→ 2 last annual reports and follow-up of non-compliance

No specific systematic item of control on justification and optimisation but questions (during inspection) on:

Justification

- Describe how a medical referral for a NM procedure can be rejected or modified by NM physician
- Description of the validation of the medical order by a nuclear medicine physician
- Description of the software used by the radiopharmacist
- …

Optimization

- Description of the parameters used in the SPECT-CT, how the injected activity can be lowered…
- …

Scope of Inspection in nuclear medicine - 5

Before 2018: ~ 40 items *(no graded approach)*

Inspections in 182 NM units between 2015 to 2017

Few items for protection of patient

- Comparison and analysis of the local diagnostic reference levels to the national DRL : OK in 87%
- External quality control OK in 95%
- Professionals trained to the patients radiation protection: **OK in 76%**

→ *Results for 2018 with mandatory items of control?*

Inspections in nuclear medicine – Coming soon…

Evaluation of the new method of inspection with mandatory items of control (for all medical activities)

- Duration of inspection
- Analysis of these items
- Add other items ?

In 2019,

- In addition of MIC, a thematic form on notified events in NM

(since the NM department registration system to the ASN notification, and the lessons learned from past events)

Thanks for your attention