Experience from new IAEA training workshops for inspectors

HERCA MedInspector 2018

How to inspect justification and optimization in Nuclear Medicine

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My background

- MSc. In Applied Physics, University of Jyväskylä
- 2009-2011 Medical Physics Intern (Radiology, Radiotherapy and Nuclear Medicine), Central Finland Health Care District
- 2012 → Inspector, (Nuclear Medicine & Radiotherapy), STUK

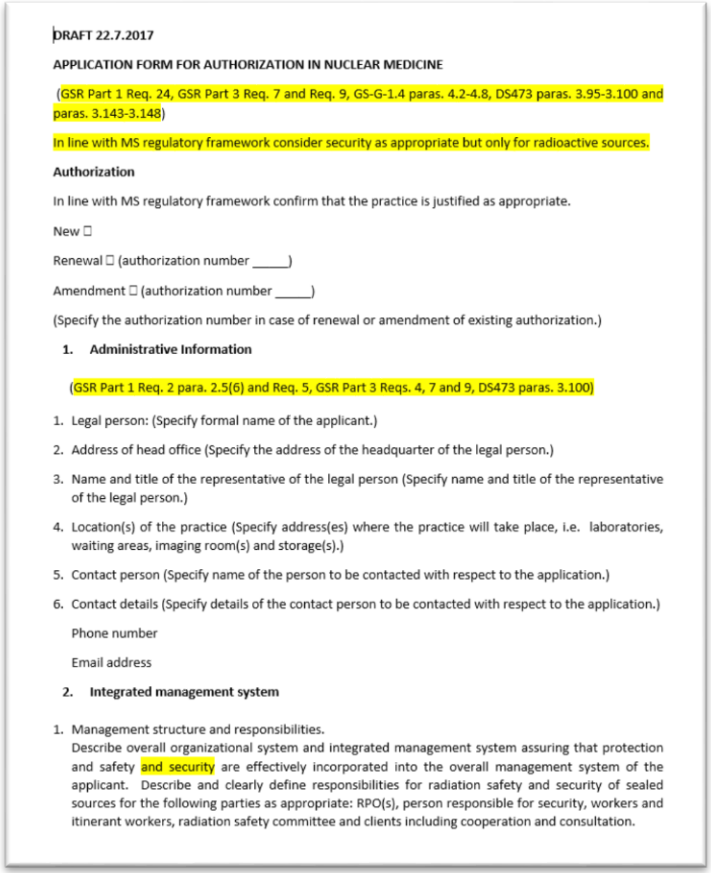
Workshops

- Regional Workshop on Authorization and Inspection of Radioactive Sources in Radiotherapy Facilities, Cairo, Egypt, 27 September – 2 October 2015
- Regional Workshop on Authorization and Inspection of Radiation Sources in Nuclear Medicine Facilities, Vienna, Australia, 4 – 8 April 2016
- National Workshop on Authorization and Inspections of Radiation Sources in Medical and Industrial Practices, Vienna, Austria, 11 – 15 July 2016
- Workshop on Authorization and Inspection of Radiation Sources in Radiotherapy Practices, Hanoi, Viet Nam, 2017
- National Workshop on Definition of the Working Parameters of a Joint Group of the Ministry of Health and the Nuclear Regulatory Authority on the Licensing of Hybrid Imaging Equipment on, Buenos Aires, Argentina, 2018

Typical Agenda: Workshop on Authorization and Inspection of Radiation Sources in XX

- Day 1, Authorization
  - Opening and presentation of participants
  - Overview Presentations by Experts on the Process and Procedures for Notification and Authorization of Radiation Sources
  - Practical session on the Process and Procedures for Notification and Authorization of radiation sources in XX (Eg. Nuclear Medicine, Radiotherapy, X-ray diagnostics)
  - Homework: Translate IAEA's authorization form to local language

- Day 2, Authorization
  - Practical session on the Process and Procedures for Notification and Authorization of radiation sources in XX, *Continued*
  - Review and finalization of the updated application form for authorization and associated documentation



DRAFT 22.7.2017

APPLICATION FORM FOR AUTHORIZATION IN NUCLEAR MEDICINE

(GSR Part 1 Req. 24, GSR Part 3 Req. 7 and Req. 9, GS-G-1.4 paras. 4.2-4.8, DS473 paras. 3.95-3.100 and paras. 3.143-3.148)

In line with MS regulatory framework consider security as appropriate but only for radioactive sources.

Authorization

In line with MS regulatory framework confirm that the practice is justified as appropriate.

New □

Renewal □ (authorization number _____)

Amendment □ (authorization number _____)

(Specify the authorization number in case of renewal or amendment of existing authorization.)

1. **Administrative Information**

(GSR Part 1 Req. 2 para. 2.5(6) and Req. 5, GSR Part 3 Reqs. 4, 7 and 9, DS473 paras. 3.100)

1. Legal person: (Specify formal name of the applicant.)
2. Address of head office (Specify the address of the headquarter of the legal person.)
3. Name and title of the representative of the legal person (Specify name and title of the representative of the legal person.)
4. Location(s) of the practice (Specify address(es) where the practice will take place, i.e. laboratories, waiting areas, imaging room(s) and storage(s).)
5. Contact person (Specify name of the person to be contacted with respect to the application.)
6. Contact details (Specify details of the contact person to be contacted with respect to the application.)

   Phone number

   Email address

2. **Integrated management system**

1. Management structure and responsibilities.
   Describe overall organizational system and integrated management system assuring that protection and safety and security are effectively incorporated into the overall management system of the applicant. Describe and clearly define responsibilities for radiation safety and security of sealed sources for the following parties as appropriate: RPO(s), person responsible for security, workers and itinerant workers, radiation safety committee and clients including cooperation and consultation.

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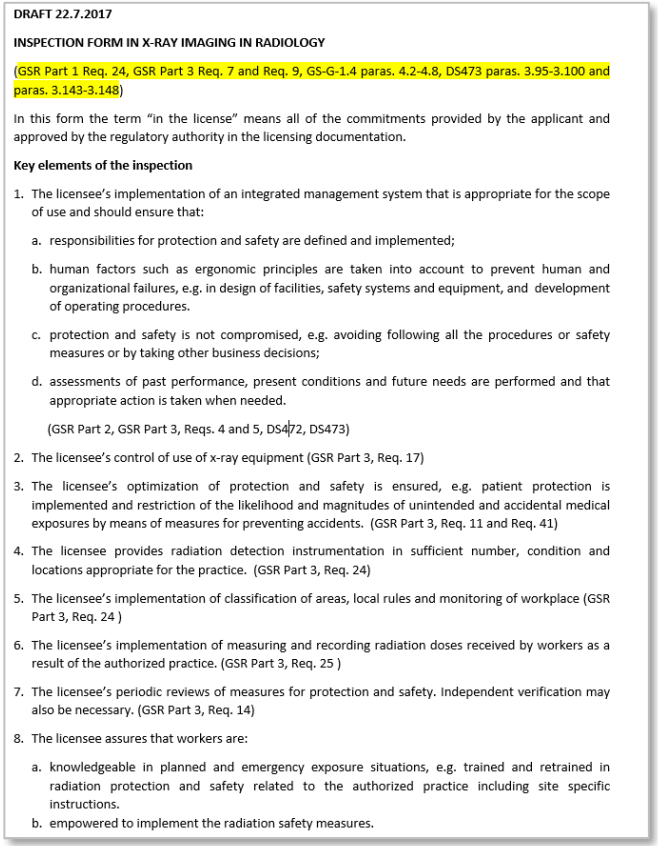
SÄTEILYTURVAKESKUS
STRÅLSÄKERHETSCENTRALEN
RADIATION AND NUCLEAR SAFETY AUTHORITY

Typical Agenda: Workshop on Authorization and Inspection of Radiation Sources in XX

- Day 3, Inspection
  - Overview presentations by Experts on the Process and Procedures for Inspection of XX Sources
    - Preparation for unannounced and announced inspection
    - Conduct of inspection
    - Inspection protocols and methods
    - Necessary equipment for the inspection
  - Annual Inspection Programme Based on Graded Approach
  - Introduction to draft of IAEA's inspection form for XX
  - Homework: Translate IAEA's authorization form to local language



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INSPECTION FORM IN X-RAY IMAGING IN RADIOLOGY

(GSR Part 1 Req. 24, GSR Part 3 Req. 7 and Req. 9, GS-G-1.4 paras. 4.2-4.8, DS473 paras. 3.95-3.100 and paras. 3.143-3.148)

In this form the term "in the license" means all of the commitments provided by the applicant and approved by the regulatory authority in the licensing documentation.

Key elements of the inspection

1. The licensee's implementation of an integrated management system that is appropriate for the scope of use and should ensure that:
   a. responsibilities for protection and safety are defined and implemented;
   b. human factors such as ergonomic principles are taken into account to prevent human and organizational failures, e.g. in design of facilities, safety systems and equipment, and development of operating procedures.
   c. protection and safety is not compromised, e.g. avoiding following all the procedures or safety measures or by taking other business decisions;
   d. assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

   (GSR Part 2, GSR Part 3, Reqs. 4 and 5, DS472, DS473)
2. The licensee's control of use of x-ray equipment (GSR Part 3, Req. 17)
3. The licensee's optimization of protection and safety is ensured, e.g. patient protection is implemented and restriction of the likelihood and magnitudes of unintended and accidental medical exposures by means of measures for preventing accidents. (GSR Part 3, Req. 11 and Req. 41)
4. The licensee provides radiation detection instrumentation in sufficient number, condition and locations appropriate for the practice. (GSR Part 3, Req. 24)
5. The licensee's implementation of classification of areas, local rules and monitoring of workplace (GSR Part 3, Req. 24)
6. The licensee's implementation of measuring and recording radiation doses received by workers as a result of the authorized practice. (GSR Part 3, Req. 25)
7. The licensee's periodic reviews of measures for protection and safety. Independent verification may also be necessary. (GSR Part 3, Req. 14)
8. The licensee assures that workers are:
   a. knowledgeable in planned and emergency exposure situations, e.g. trained and retrained in radiation protection and safety related to the authorized practice including site specific instructions.
   b. empowered to implement the radiation safety measures.

Typical Agenda: Workshop on Authorization and Inspection of Radiation Sources in XX

- Day 4, Onsite (mock) inspection
  - Preparations for an inspection
  - Transportation to the hospital and an inspection
  - Debriefing of the inspection

- Day 5, Reporting and closing of workshop
  - Drafting an inspection report and recording findings from the inspection
  - Discussion of open matters and closing

Challenges

- Lack of knowledge of Nuclear Medicine
  - Most inspectors haven't worked at NM department, so they don't know how things are done
- Inspections are typically conducted with old IAEA checklists and there is no deeper knowledge about questions
  - What is the legal basis?
  - Why is this question asked?
  - How radiation safety is improved by this question?

5. RESPONSIBILITIES
Justification and Optimization [BSS App. II]

	Yes	No
Procedures are authorized by appropriately Qualified Practitioners, in accordance with the medical speciality for which the radioactive material is going to be applied to patients? (e.g. cardiologists, endocrinologists, nephrologists, etc.)		
Has an appropriately Qualified Practitioner been designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this practitioner ensure that procedures are justified?		
If yes, how the practitioner says is this achieved?		
Is the activity of radio-pharmaceuticals administered to patients within the range considered acceptable by the profession and the regulatory body?		
At what frequency is this reviewed, by whom and when reviewed last?		
Does the facility undertake research involving exposure of humans to radiation?		
If yes, are procedures in place ensuring compliance with the Helsinki Declaration, and guidelines observing the requirements of the Council for International Organizations of Medical Sciences and of the World Health Organization?		

Checklist for Nuclear Medicine, IAEA-TECDOC-1526, Inspection of Radiation Sources and Regulatory Enforcement

Challenges & Tips

Challenges

- Regulation of radiation safety is divided between many authorities.
  - E.g. Use of unsealed and sealed sources is handled by on authority and medical use of X-rays is authorized by another regulator
- Language barriers
  - Participants might say that they understood (yes, yes), but really they don't
  - Use questionnaires, exercises and homework to verify that participants really understood what was thought

Tips

- Spend some time to understand local situation
  - It's a good idea to ask in advance the authority to give a presentation on the first day about their authorization and inspection process
  - Adapt!

Tips & Ideas

- Have a friend with you on the workshop
  - It is far easier to survive weeks workshop with colleague with whom one can share the burden of preparing material
  - Also when one is giving a presentation the other can search information (e.g. for a question raised during presentation)
- Prepare well for the workshop, but be ready to change plans.
  - Typically workshops don't go as they were planned.
- Be humble and don't assume that all you have all the knowledge
  - Now days a lot of information is freely available and motivated person can learn much reading online material (e.g. IAEA)
- Interact, don't just give lectures
  - Spending a whole week giving lecture after lecture is probably useless.
  - If workshop doesn't require any effort from participants then they probably won't remember a thing.
- Think how workshop could have a lasting effect on the authority and to the participants
  - Develop material (guides, forms for authorization and inspection) that will be used by the authority after the workshop
  - Make participants work at the workshop
  - Test that participants have understood presentations with (online) questionnaires