

Protection and Safety Programme Advice – Nuclear Medicine

A protection and safety programme tells how the licensee will protect people and the environment. This programme should include management arrangements, procedures and equipment.

After FANR has reviewed and accepted the programme, it will become a part of the licence. That is, licensees must meet the commitments they have made in these programmes.

A nuclear medicine protection and safety programme should have the following:

1. Safety Assessment

This is the basis for the protection and safety programme. It should deal with each type of radiation source used by the licensee, and include the licensee's equipment, procedures and operations. It should estimate the doses due to routine operations and the potential doses due to accidents. Based on this information it should specify the radiation protection equipment and procedures that the licensee needs.

A licensee that is already in operation should conduct a safety assessment to check whether any additional safety measures are needed.

2. Information about the licensee

Include

- The number, types and activities of the radiation sources that the licensee uses
- The quantity of radioactive material present at the facility
- The number of staff who work with radiation and their areas of expertise
- A floor plan showing areas for examination and treatment and for preparing and storing radioactive materials
- Patient workload

3. Radiation safety policies

Provide a commitment to comply with FANR regulations and licence conditions. Include a commitment to support this protection and safety programme.

Include a procedure to notify FANR at least thirty days before any significant changes to equipment, responsible staff or radiation protection arrangements.

4. Management structure

Include an organization chart showing the reporting chain through clear lines of responsibilities and accountability covers whole process (from import to dispose). Include the duties and authorities for radiation safety of managers, supervisors and staff. Identify roles of radiation protection officers (RPO) and their duties, authorities (documented delegation) and access to managers. Include a requirement that staff must be qualified for their duties. Include a procedure for making sure that staff understand and acknowledge their duties.

Include a radiation protection committee. Members usually include the chief nuclear medicine physician, a medical physicist, a radiopharmacist, the RPO, a maintenance supervisor and a responsible hospital manager.

5. Occupational Protection

Include what will be done to keep workers' doses within your dose constraints (an occupational dose constraint of 6 mSv/year is regarded as reasonable). Include a procedure to train workers about what they should do to protect themselves from radiation

Include how pregnant workers are encouraged to notify management and how management will adapt their working conditions to protect the foetus without excluding the women from work.

Include how persons under 18 are protected from radiation

Specify any controlled areas or supervised areas, and say why they were established. Controlled areas usually include rooms for storing and preparing radiopharmaceuticals, examination and treatment rooms and wards for therapy patients. Include how these areas are monitored, how access is restricted and what protective measures are used. Provide for easy workplace decontamination.

Personal protective equipment should include

- Protective eyewear for staff involved in surgery on patients who have been given therapeutic doses
- Gloves and protective clothing for staff working with unsealed sources
- Syringe shields and transparent lead shields, handling tools, appropriate preparation area (hot lab) for working with radiopharmaceuticals. Fume hoods if needed

6. Individual and workplace monitoring

- a) For individual monitoring, provide written procedures for worker dose assessments. Include internal exposures if needed. Include how workers who are monitored are identified. Include arrangements for using an approved dosimetry service and rules for returning and changing dosimeters. Include how the RPO will review doses and how accumulated doses will be recorded. Include procedures for dealing with worker overexposures and lost or damaged dosimeters. Include investigation levels. Provide procedures so that dose records contain the information FANR requires, are kept as long

as FANR requires, and are made available to workers. Include a procedure for reporting worker doses to FANR every six months.

- b) For workplace monitoring, include how controlled and supervised areas are monitored for radiation and contamination and how often they are checked.
- c) Monitoring devices should include occupational personal dosimeters, finger ring dosimeters as needed and a pancake Geiger-Mueller counter or other low-range detector capable of detecting alpha and beta contamination.
- d) Health surveillance should include assessing workers' fitness for their tasks and detecting any occupational health issues they may have. Include preventing deterioration of workers' health, and evaluating how effective the licensee's radiation and contamination control measures are. Provide for asking whether the workplace needs to be changed to improve workers' health.

7. Patient Exposure Protection

Include assigning responsibility for patient protection to a medical practitioner such as the department head, nuclear medicine physician or chief medical officer. Include assigning responsibility for advising on imaging and quality assurance to a specific qualified expert.

Provide a procedure for justifying medical exposures. Include how patients' exposures will be kept to the minimum required for effective diagnosis and treatment. This procedure should take guidance levels and information from previous examinations or treatments into account to avoid unnecessary additional exposures.

Include how women who are pregnant or breast feeding will be protected. Provide for signs in appropriate languages and procedures for questioning female patients.

Provide a procedure for calibrating radiopharmaceuticals in terms of their activity at the time they are administered, and how the activity meter will be calibrated.

For accidental patient exposures, include procedures to investigate and report:

- Any therapeutic treatment given to the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or causing a dose significantly different from what was planned;
- Any diagnostic exposure much greater than planned or causing doses repeatedly and significantly higher than guidance levels;
- Any equipment failure, accident, mistake or other unusual event that might have made a patient get an exposure significantly different from what was planned.

For accidental patient exposures, include procedures to estimate the doses received, to decide on the corrections needed and to make those corrections.

Include how justification and optimization procedures will be reviewed. Include how records will be maintained for at least five years so that past doses can be assessed, including doses from radiopharmaceuticals.

8. Public Protection

Provide the licensee's procedures for keeping doses to the public below an acceptable public dose constraint of 0.1 mSv/yr. (FANR will consider a dose constraint of up to 0.3 mSv/year if the Licensee provides a reason for why a Dose Constraint of 0.1 mSv/year is impractical¹.) Include how public exposures will be monitored and recorded to be sure these constraints are met, such as surveys. Include protecting family members, caregivers, and visitors. Include shielding designs and use of controlled and supervised areas. Include waiting areas, examination, treatment and recovery rooms and wards for patients containing radioactivity. Include procedures for moving radiation sources and patients containing radioactivity inside the hospital. Include patient release criteria.

9. Safety of generators, sources, equipment and instruments

Discuss how the licensee will make sure that it buys the right sources and equipment, including instruments, for its needs and how it will make sure they meet international quality standards.

Provide inspection, calibration & maintenance procedures. Discuss how equipment and instruments will be tested according to international standards. Include software.

Describe any personal protective equipment that is used and the procedures for its use, inspection and maintenance.

Include how the licensee will keep sources and generators secure, including

- Keeping an inventory of all sources and generators, including their descriptions, where they are located and who is assigned to keep the inventory include criteria to submit to FANR.;
- Keeping sources and generators from being stolen or damaged, and keeping unauthorized persons from using them either where they are used or where they are stored.

This section should also include procedures for controlling sources and generators, including

- Procedures to keep them from being transferred unless the receiver is authorized to have them;
- Procedures to notify FANR after receiving or transferring them;
- Procedures to notify FANR if a source or generator is stolen or damaged, as required by REG-24, Article (19); and
- Procedures to send FANR the licensee's inventory of sources and generators twice each year

¹ See FANR Regulatory Guide 007, 'Radiation Safety', page 11.
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10. Operating procedures

These should be written procedures and local rules for workers to follow. They should be clearly displayed or easy for workers to find and should be written in all of the languages that the workers may use. They should include

- Procedures for receipt, storage and disposal of radioactive sources (by/ or under supervised of qualified and authorized person), including remove source from transport container;
- Procedures for safe handling of radiation sources including preparing and administering radiopharmaceuticals
- Procedures for calibrating dose calibrators
- Procedures for decontaminating the workplace

11. Employee training

Provide the radiation safety training program for all workers who work directly with sources or generators. The training should emphasize the procedures the workers must follow. Include how worker attendance at training will be recorded and how the workers will be tested to make sure the training has been effective. As well as the periodic of the re-training should be identified

12. Incident reporting and investigation

Provide procedures for reporting incidents and accidents to FANR and procedures for investigating them. Include procedures to meet the reporting requirements in of FANR-REG-24, Articles (19) and (41).

13. Emergency Response Plan

Begin with a list of predictable incidents and accidents and the procedures that will be followed to deal with them. Include immediate actions to minimize doses to patients, staff and the public. Include how the public will be kept away from affected areas until conditions have been returned to normal.

Describe the duties of each person who will respond to the emergency. Include nuclear medicine technologists, the nuclear medicine specialist and any qualified experts. Include the names and complete contact information for these persons.

Provide for simple instructions to be clearly visible and for any equipment needed for emergency response. Include reporting procedures, along with the contact information needed to report accidents to all responsible authorities.

Provide for Emergency Response training that includes drills, exercises and refresher training.



14. Import/Export

Provide the licensee's procedure for getting permission from FANR to import and export sources. Licensees must ask FANR for a permit in advance of each shipment.

15. Transportation

Provide procedures for receiving packages containing radioactive sources. Include procedures for surveying them, confirming the shipping documents, and notifying FANR that the packages have been received. Provide procedures for training workers who do any of these things.

Licensees who send sources away from their facilities or transport them to other locations should provide procedures for doing these things. These procedures can be developed using FANR Regulatory Guide 006, Transportation Safety.

16. Waste management

Provide procedures to minimize, characterize, segregate, treat, store, document and dispose of wastes. Include sources that are no longer used.

17. Quality Assurance

Provide the licensee's Quality Assurance (QA) programme. Include a process for writing procedures; for changing them and for documenting the changes. Also include a process for confirming compliance with the procedures.

Include procedures to make sure safety equipment and safety systems are checked regularly and that problems are corrected. Include quality assurance of instruments used for calibration and clinical dosimetry.

Include procedures for periodically reviewing and auditing the licensee's safety performance. Include the performance of this protection and safety programme. Include corrective action procedures.

Resource Information

A thorough description of a Nuclear Medicine protection and safety programme is provided in Appendix I of IAEA Safety Series Report No. 40, Applying Radiation Safety Standards in Nuclear Medicine, Pub1207, 2005.