Guidelines for the Clinical Use of ^{18}F-FDG-PET/MRI 2012 (Ver 1.0): Part 2

Ukihide Tateishi[1], Yuji Nakamoto[2], Koji Murakami[3], Tomohiro Kaneta[4], Akira Toriihara[5], Munenobu Nogami[6], Tadaki Nakahara[3], Kazunori Kubota[5], Mitsuaki Tatsumi[7], Mototaka Miyake[8], Yumiko Oishi Tanaka[9], and Seiji Kurata[10]

[1]Department of Radiology, Yokohama City University Graduate School of Medicine
[2]Department of Diagnostic Radiology and Nuclear Medicine, Kyoto University Graduate School of Medicine
[3]Department of Radiology, Keio University Graduate School of Medicine
[4]Department of Diagnostic Radiology, Tohoku University Graduate School of Medicine
[5]Department of Radiology, Tokyo Medical Dental University Graduate School of Medicine
[6]Department of Radiology, Kochi University Hospital
[7]Department of Radiology, Osaka University Graduate School of Medicine
[8]Department of Diagnostic Radiology, National Cancer Center Hospital
[9]Department of Radiology, Graduate School of Comprehensive Human Sciences, University of Tsukuba
[10]Department of Radiology, Kurume University Graduate School of Medicine

Address correspondence to: Ukihide Tateishi, MD, Department of Radiology, Yokohama City University Graduate School of Medicine, 3-9, Fukuura, Kanazawa-ku, Yokohama, 236-0004. Tel: +81-45-787-2696, Fax: +81-45-786-0369. E-mail: utateish@yokohama-cu.ac.jp

Radiological Safety Management

I. Safety Management of PET Imaging Systems

To ensure the medical safety of all persons involved in PET examination, details of appropriately implementing the examination and rationally managing radiation exposures are given in the Guidelines for Ensuring Safety During the Conduct of FDG-PET Examinations (2005)[1)].

1) Roles and Responsibilities of the Manager, etc., Involved in FDG-PET Examinations
2) Operating Procedures for FDG-PET Examination
3) Quality Control of FDG Chemicals
4) Quality Assurance and Quality Control of PET Examination Systems
5) Safety Education and Training for Medical Radiology Workers
6) Notes and Instructions for Patients and Patient Caregivers, etc.
7) Matters to Be Arranged at the Department of Nuclear Medicine Where FDG-PET Examinations are Conducted
8) Management of Radioactive Wastes
9) Transportation of FDG Chemicals to Locations Within Business Establishments, etc.
10) Matters to Be Disclosed Related to the Conduct of PET Examinations as Required by the Medical Service Act

1. Roles and Responsibilities of the Manager, etc., Involved in FDG-PET Examinations

1.1 Safety management system for medical radiology

The manager of the hospital or clinic shall comply with the standards for protection against medical radiation from radioisotopes for positron emission tomography stipulated in the Enforcement Regulations of the Medical Service Act, and the medical institution conducting FDG-PET examination shall establish a systematic safety management system so as to achieve the purpose of ensuring safety and protecting against medical radiation on the basis of the ALARA (as-low-as-reasonably-achievable) principle. The medical institution shall also express and raise awareness about its philosophy and policy concerning safety management for medical radiation among its medical radiology workers.

1.2 Committee on safety management for medical radiation

To optimize radiation protection in the FDG-PET examination, the manager of the hospital or clinic shall organize a committee on safety management for medical radiation comprising radiologists, radiation protection supervisors (if the Radiation Hazard Prevention Act applies),

medical radiology technicians, pharmacists, nurses, etc. The manager shall hold a committee meeting periodically and whenever required to discuss the matters shown below. All decisions at the meeting must be disclosed in writing to the relevant departments.

1.3 Matters to be discussed by the committee on radiation safety management at medical institutions

1) Matters concerning the development and update of operating procedures for reducing exposure doses from FDG-PET examination in medical radiology workers
2) Matters concerning education required to ensure radiation protection of medical radiology workers
3) Matters concerning notes and instructions required to ensure radiation protection of personnel, etc., other than medical radiology workers (temporary visitors), who are involved in FDG-PET examination
4) Matters concerning the determination of radiation exposure in medical radiology workers and assessment of the findings of their health checkups
5) Matters concerning quality assurance and quality control of FDG chemicals and FDG pharmaceuticals (hereinafter together referred to as “FDG chemicals, etc.”) for FDG-PET examination and PET examination systems
6) Matters concerning analytical assessments of medical incidents or malpractices, etc., related to FDG-PET examination and actions to be taken to prevent their recurrences
7) Matters concerning internal audit results
8) Other matters concerning requirements for radiation protection during the FDG-PET examination

2. Operating Procedures for FDG-PET Examination

1) Roles and responsibilities of medical radiology workers in FDG-PET examination
2) Protocol including patient traffic lines in FDG-PET examination
3) Quality control of FDG chemicals
4) Confirmation of patient doses of FDG chemicals, etc.
5) Quality assurance and quality control of PET examination systems
6) Patient identification
7) Clinical procedures, including post-examination image analysis and data display
8) Cautions, notes, instructions, etc., for patients, etc.
   (a) Cautions and instructions for patients receiving FDG chemicals, etc.
   (b) Cautions and instructions concerning radiation protection for caregivers and patients other than subjects of FDG-PET examinations

9) Other matters concerning radiation safety

3. Quality Control of FDG Chemicals

1) Work environment
2) Work environment standards
3) Work standards
4) Production control systems
5) Records
6) Automated synthesizers
7) Quality standards for 2-deoxy-2-fluoro-D-glucose (18F) injection liquid
8) Precautions

4. Quality Assurance and Quality Control of PET Examination Systems

1) To confirm the normal operation and other functions of the system to be used for FDG-PET examinations after its delivery to the examination facility and before its use in actual examinations, the medical radiology worker shall conduct a system acceptance test and confirm that it functions as described in the manufacturer's instruction manual with the attendance of the distributor of the system. The medical radiology worker shall also periodically check system functions related to the approval criteria to assure their quality.
2) The medical radiology worker, etc., shall implement inspection and maintenance programs for the safety functions, of the system used for FDG-PET examination.
3) The quality assurance inspection shall include a check of image acquisition time, method of image acquisition, and method of image processing (method of image reconstitution, filters, etc.). The performance of the computer system used to acquire and process images shall be confirmed and test measurements shall also be included.
4) If discovering a significant defect in the system, the medical radiology worker, etc., shall notify the manager of the hospital or clinic about remedial measures taken temporarily, the subsequent repairs made by the manufacturer, and the results of tests performed before restarting the clinical use of the system. Furthermore, the manager shall also alert all medical radiology workers who operate the system to these facts by publicly announcing them and communicating them in writing.

For details of quality assurance and quality control of PET examination systems, the content of the Guidelines for PET Examination Using In-house-produced FDG (2nd Edition) prepared by the Japanese Society of Nuclear Medicine[2] shall apply. For the maintenance of imaging equipment, the Guidelines for PET Examination Using In-house-produced FDG (2nd Edition) [2)]

and the Guidelines for Imaging Techniques in FDG-PET Examination[3)] shall serve for reference purposes.

5. Safety Education and Training for Medical Radiology Workers

The manager of the hospital or clinic shall provide education and training, including the matters shown below, for medical radiology workers, etc., involved in FDG-PET examination so as to ensure their radiation protection and medical safety.

5.1 Standard patient-absorbed doses and effective doses in FDG-PET examination

While a wide variety of reports are available on exposure doses in subjects receiving FDG, the report of the International Commission on Radiological Protection (ICRP) Publication No. 80 is often cited. Values given in the publication are shown in Table 1[4)]. The effective dose obtained by administering 185 MBq (5 mCi) to an adult human is 3.5 mSv. The exposure dose from an ordinary transmission scan procedure with ^{68}Ge-^{68}Ga source is approximately 0.25 mSv.

Table 1. Radiation doses from exposure to FDG (organ-averaged absorbed doses and effective doses)

Organ	Adults	15-year-old	10-year-old	5-year-old	1-year-old
Red pulp (mGy/MBq)	0.011	0.014	0.022	0.032	0.061
Urinary bladder wall (mGy/MBq)	0.160	0.210	0.280	0.320	0.590
Effective dose (mSv/MBq)	0.019	0.025	0.036	0.050	0.095

For exposures to radiation by subjects, the “Radiation Exposure Management” section in the Guidelines Concerning the Use of FDG-PET for Cancer Screening (2007) [5)] prepared by the Japanese Society of Nuclear Medicine and the “Dosing Standards” and “Exposure Doses (Calculated by the MIRD Method)” sections in the Guidelines for PET Examination Using In-house-produced FDG (2nd Edition) [2)] established by the Japanese Society of Nuclear Medicine shall also serve for reference purposes.

5.2 Radiation protection for medical radiology workers

5.2.1 Principles of protection against medical radiation

To minimize radiation exposure in medical radiology workers involved in the preparation of FDG chemicals and/or PET examination and public radiation exposure from patients

undergoing PET examination as the source of radiation, it is necessary to reduce the risk to the lowest possible level within a reasonably achievable range for medical radiology workers handling FDG chemicals, etc., and patients receiving them, by making the best use of the three principles of radiation protection (time, distance, shield), and taking into account social and economic factors.

5.2.2 Reduction of exposure to radiation associated with PET examination work
PET radionuclides have short half-lives, so often large amounts of radioactivity emitting high-energy annihilation photons need to be handled. Therefore, the level of exposure in medical radiology workers is anticipated to be high during the production and dispensing of FDG and administration of FDG chemicals, etc. It is necessary to take radiation protection measures appropriate to the characteristics of PET tracers. Because the exposure level depends on the time during which radionuclides are handled and distance from the source, the medical radiology worker must be very skilled in the operating procedures. For example, it is necessary to make efforts to shorten the time during which the worker is in contact with the patient receiving PET chemicals, etc., including patient guidance without approaching him or her at a distance greater than the minimum level allowed, by previously providing information (i.e., an explanation of the nature and procedures of the examination, the location of the examination room, and the manner of moving from the waiting room) before the FDG examination begins. In cases where urine excreted by the patient receiving FDG chemicals, etc., is pooled for a variety of medical reasons in the controlled area (pooled urine), it must be considered a source of radiation on the day of FDG administration.

5.2.3 Medical radiology workers in pregnancy
After being told by a medical radiology worker that she is pregnant, the manager of the hospital or clinic is obliged to prevent exposure levels including the internal effective dose and the abdominal surface external equivalent dose from exceeding 1 mSv and 2 mSv, respectively, during her gestation. If these dose limits are expected to be exceeded, the manager of the hospital or clinic must consider other actions, including changing worker duties, in relation to the continuance of the medical radiology work by the medical radiology worker. In implementing the measures, consent must be obtained from the medical radiology worker.

5.2.4 Radiation exposure associated with FDG production and dispensing work
5.2.5 Reduction of exposure doses associated with administration of FDG chemicals, etc.
5.2.6 Exposure doses associated with PET imaging
5.2.7 Exposure from external sources

6. Notes and Instructions for Patients and Patient Caregivers, etc.

7. Matters to Be Arranged at the Department of Nuclear Medicine Where FDG-PET Examinations are Conducted

7.1 Standards for buildings and facilities containing radioisotopes for use in positron emission tomography, stipulated in the Enforcement Regulations for the Medical Service Act

As required to ensure radiation protection in the department of nuclear medicine that undertakes FDG-PET examinations, the rooms, etc., listed below shall be available in the department as stipulated in Article 30.8.2 of the Enforcement Regulations for the Medical Service Act and the notification of its enforcement. The new provisions on the availability of a PET waiting room and operating platform in the Enforcement Regulations mainly aim to reduce radiation exposure levels from PET examinations in individuals other than subjects.

1) Positron preparation room: A room where FDG chemicals, etc., are prepared and dispensed
2) Positron medication and imaging rooms: A room where FDG chemicals, etc., are administered to the patient (medication room) and a room where a PET system is installed and imaging is performed
3) Positron waiting room: A room where the patient receiving FDG chemicals, etc., rests before undergoing the FDG-PET examination
4) Operating platform: A place where the operation console is situated
5) Display of signs and cautions

7.2 Requirements for buildings, facilities, etc.

In PET facilities, it is necessary to design buildings and facilities so that radioprotection of workers is secured by separating the workers from the source of radiation by the longest distance possible.

II. Safety Management for MRI Equipment

Unlike PET/CT equipment, PET/MRI equipment does not emit radiation. However, MR equipment produces an intense static magnetic field. Incidents due to MR equipment magnetic fields can occur; it must be kept in mind that PET/MRI examination, like ordinary MR examination, is never completely safe. Some reviews or guidelines for safe implementation of MR examination have been published[8-13].

Basic Matters for Safety Management

1. Safety Management for Static Magnetic Fields

1.1 Physical action

1.1.1 Extracorporeal metal objects

If carelessly carried into the examination room, any ferromagnetic objects (oxygen cylinders, wheelchairs, stretchers, IV drip stands, tools, etc.) can become a missile under the influence of the magnetic field. Essentially, the strength of a magnetic field is inversely proportional to the cube of the distance from the magnetic center of the coil in both the axial and perpendicular directions. Conversely, active shields significantly decrease the area of coverage of the magnetic field, so that an object is suddenly attracted to the magnet on approaching the vicinity of the magnet and can thereby lead to an incident. It is necessary to raise awareness that unforeseeable incidents can occur in the special environment of the PET/MRI room.

1.1.2 Intracorporeal metals

Metals in the subject's body cannot always be removed before starting the examination; the physician shall endeavor to detect such metals by patient interviews and the like. However, the presence of an intracorporeal metal to be removed in advance or contraindicated for MRI examination can be unnoticed, making it difficult to ensure safety. Although the medical devices and equipment that are contraindications for MRI examination, such as cardiac pacemakers, defibrillators, and cerebral aneurysm clips and cochlear implants of magnetic materials, are widely known, the possible influences of metals, stents, coils, and other materials used in orthopedics on the MRI examination is not always known.

1.2 Biological action of static magnetic fields

According to the guidelines by the US Food and Drug Administration (FDA), magnetic fields of up to 8 Tesla are not considered to pose significant risks to the human body. Meanwhile, the influence of chronic exposure to a high-magnetic-field environment on the human body and its safety remain unknown.

2. Radio Frequency (RF) Waves

The specific absorption rate (SAR) per unit weight is proportional to the square of each frequency and static magnetic field strength. Other factors that can influence SAR values include mechanical factors such as pulse type and number, duration, repeat cycles, and type of coil, as well as biological factors such as tissue electroconductivity, specific gravity, anatomical region, degree of perfusion, and body weight. Regarding the choice of a method of imaging, the turbo spin echo technique, which often employs 180° pulses, produces increased SARs. The body temperature rise due to the heat generation from RF-induced currents is relatively small, and hence usually poses no problem, provided that the subject retains his or her innate ability to control body temperature. However, special attention is required in elderly persons, children, and other subjects unable to control body temperature. Additionally, dentures, gold crowns, and other metal objects, as well as tattoos, art makeup, and transdermal adhesive plasters such as Nitroderm, which contains aluminum on the surface of the plaster, can cause burns if present in the field of RF coil excitation.

3. Percent Changes over Time in Gradient Magnetic Field

Fast switching of gradient magnetic fields produces an induced voltage and induced current, resulting in heat generation and nerve stimulation. With the increase in percent change over time in the gradient magnetic field, a greater electric current (eddy current) is produced in the human body, acting as a resistor, and thus has an increased influence on peripheral nerves and cardiac muscles. However, this is not considered to be problematic, provided that the current safety criteria are met, because it is estimated that cardiac stimulation cannot be induced without a change in gradient magnetic field that is much more intense, or faster, than the field change occurring under normal operating conditions of commercially available MRI equipment.

4. Noise

When the orientation of the electric current in the gradient magnetic field coil changes rapidly, the resulting force causes the gradient magnetic field coil to vibrate and produce a loud noise.

5. Guidelines for the Delivery of MRI Equipment

Regarding safety management concerning the delivery of MRI equipment, a great deal of knowledge about safety collected by member companies of the Japan Medical Imaging and Radiological Systems Industries Association was put into the Guidelines for Delivery of Magnetic Resonance Equipment prepared by the association in 2006.

(1) Specifications for power supply and grounding

(2) Specifications for MRI facilities and their environments

(3) Package insert to be distributed at the time of equipment delivery

MRI equipment

WARNINGS

1) All metal objects worn on various parts of the human body should be removed before examination.

2) A person who is suspected of using difficult-to-remove metal powders, such as those used in cosmetics or tattoos, should be examined with care.

3) Special measures should be taken to prevent eyeball damage by fine metal pieces, etc., and protect against the adverse effects of sound on the ear.

4) The patient should be checked before examination to ensure that none of the CONTRAINDICATIONS/PROHIBITIONS below apply.

CONTRAINDICATIONS AND PROHIBITIONS

1) No examination should be performed while the subject wears any patch containing an electroconductive metal.

2) No examination should be performed on a patient who wears or has a metallic implant including metal powder, cardiac pacemaker, implantable nerve stimulator, cerebrospinal fluid drainage tube, etc.

3) Details of contraindications and prohibitions should be confirmed in the Contraindications for Coadministration under the Drug Interactions heading in the PRECAUTIONS section.

(4) Cleanup and disinfection

(5) Magnetic attraction incidents

Because an extremely strong magnetic field is generated in the vicinity of the magnet, a considerable attractive force acts on any magnetic object close to the magnet, attracting it to the center of the gantry. Routine operation management shall be implemented to strictly prohibit carriage of any magnetic object, whatever its size, into the examination room. As it is anticipated that systems with even greater magnetic fields will be used in the future, further cautions will be necessary.

(6) Quench incidents

If a quench incident occurs in a superconducting magnet, the liquid helium evaporates and the magnetic field disappears. The resulting gaseous helium is about 700 times as bulky as the liquid helium. Because a large amount of cold fumes is produced in the vicinity of the exhaust vent of the quench piping from the superconducting magnet, access to the vicinity of the exhaust vent should be prohibited. Any leak of gaseous helium in the examination room can lower the oxygen concentration in the room and cause difficulty breathing (suffocation). To prevent this, the oxygen concentration in the room should always be monitored. Upon detection of such an abnormality by the monitor, an alarm buzzer sounds, and an emergency exhaust device is

activated to forcibly remove the gaseous helium from the examination room. In the event of a quench incident, it is necessary to take emergency measures and safety actions according to the instruction manual and appendices. In this regard, prior drills with the participation of physicians and operators are recommended. Standards for forced discharge of gaseous helium in the controlled area are being investigated.

(7) Coolant burns

(8) Burns due to induced currents during MRI examination

To prevent incidental burns due to induced currents, it is desirable that the following statement be included: Radiofrequency waves from the MRI equipment can produce induced currents in accessories such as cables and coils in contact with the patient, causing the accessories to generate heat.

(9) Emergency preparedness

Although MRI equipment is designed and installed to withstand earthquakes of average magnitude, unforeseen events can occur in epicentral earthquakes and great earthquake disasters. Although the focus of attention may differ depending on the disaster situation at the place where the MRI equipment is installed, its model, and the status of its installation, the consequences of the event must be addressed with great care and at the discretion of the manager of each facility, while bearing in mind that “unforeseeable” issues can always arise.

(10) Influences of variable magnetic fields, RF magnetic fields, and cyclotrons

When a PET/MRI system is introduced into a facility possessing a cyclotron, not only the influence of MRI system alone, but also the influence of the cyclotron on the MRI system, must be taken into account. Regarding the spatial aspects, it is necessary to ensure that the magnetic field is a sufficient distance from the cyclotron to have no influence. The manual of MR-related measurements published by the Japan Industries Association of Radiological Systems (JIRA)[9] includes a description of a 1-Gauss limitation on cyclotrons. Referring to Siemens Medical Biograph mMR, for example, the installation conditions indicated on its drawings require a minimum distance from the cyclotron of 20 m (Table 1). If the 20-meter distance cannot be secured, it is necessary to measure the variable environmental magnetic field to verify that it meets the installation environment criterion as with ordinary situations of MRI installation.

Table 1. Magnetic shielding distances between PET/MRI systems and cyclotrons (data on Siemens Medical Biograph mMR)

Disturbing influences on the magnetic field

Static
E.g. iron girders, reinforcements, especially beneath the magnet. Partially correctable by shimming of the magnet and/or compliance with minimum clearances/maximum weights.

Dynamic
E.g. moving ferromagnetic objects, electrical wiring, transformers. Avoidable when minimum clearances are observed. Minimum distance depend on moving direction and magnet orientation.
If distances are not kept please contact the Planning Department.

	Object	Minimum clearance radial (X/Y)	Minimum clearance axial (Z)	Max. weight
Giudelines for minimum clearances and maximum weights	Water cooling system	4.0 m	4.0 m	
	Wheelchairs up to approx. 50 kg	5.5m	6.5 m	
	Carts up to approx. 200 kg	6.0 m	7.0 m	
	Transformers < 1600 kVA	14.0 m	15.0 m	
	High voltage cables < 1000 A	12.0 m	5.0 m	
	Cars up to approx. 900 kg	6.5 m	8.0 m	
	Trucks up to approx. 4500 kg, Lifts	7.0 m	9.5 m	
	Cyclotron	20.0 m	20.0 m	
	Street cars, trains	40.0 m	40.0 m	
	Angiography systems with magnetic navigation	30.0 m	30.0 m	
	Reinforcement steel in the floor	* > 1.25 m below magnet center		≤ 100 kg / m²
	Iron beam mass in the floor	* > 1.25 m below magnet center		≤ 100 kg / m

* This minimum distance is required for shimming.
Distance for magnetic shielding has to be adjusted according to individual shielding requirements.

III. Safety Management for the Use of Combined PET/MRI Systems

In the use of PET/MRI systems, it is necessary to ensure the functionality and safety of each of the components, with a focus on safety security that supplements and unifies both the special features of PET chemicals and the characteristic performance/functionality of MRI equipment.

1. Safety Management System for the Use of Combined PET/MRI Systems

1.1 Safety management for use of the PET system

For PET examination, the standards stipulated in the Enforcement Regulations of the Medical Service Act should be followed to establish and operate a systematic safety management system. A "committee on safety management for medical radiation" should be organized under the responsibility of the hospital manager, and ensure protection against medical radiation[1)].

1.2 Safety management for use of the MRI system

When a hospital or clinic (hereinafter referred to as "hospital, etc.") is planning to newly introduce MRI equipment with a given level of performance, the facility is required to create a competent department, formulate in-house rules, and establish a systematic management system, etc.[14)]. In this regard, the in-house rules on MRI equipment, etc., prepared by the hospital, etc., and other systematic requirements must generally take into account the matters shown below.

(1) Creation of a competent department responsible for the systematic management of MRI systems safety
(2) Designation of access-prohibited areas (leaking magnetic field strength ≥ 0.5 mT)
(3) Nomination of MRI operators
(4) Types of MRI equipment and MRI systems
(5) In-house rules on the handling of MRI systems

1.3 Safety management for use of combined PET/MRI systems

Any place where a combined PET/MRI system is installed is a controlled area for radiation as specified in various radiation protection rules. Therefore, safety management for the use of combined systems, as well, must be implemented according to provisions included in in-house rules based on radiation safety considerations. The Committee of the hospital, etc., overseeing the safety management for use of combined systems shall include an MRI operator representing the department of MRI management, in addition to radiologists, radiation protection supervisors, medical radiology technicians, pharmacists, nurses, etc. Furthermore, MRI operators working in the PET/MRI facility shall also carry out duties as medical radiology workers.

2. Standards Concerning Facilities, etc., Involving the Use of Combined PET/MRI Systems

The facility in which a combined PET/MRI system is installed shall as a rule meet the criteria given in the present guidelines.
(1) The primary structure, etc., of the facility shall be of fireproof or incombustible material.
(2) The PET/MRI operating room shall be a room where PET chemicals, etc., are prepared (hereinafter referred to as the “positron preparation room”), PET chemicals are administered (hereinafter referred to as the “PET procedure room”), the patient receiving a PET chemical waits for examination (hereinafter referred to as the “PET waiting room”), and PET/MRI images are taken (hereinafter referred to as the “PET/MRI examination room”). Said rooms shall be separated from each other by partitions, etc. Within the operating room, PET chemicals shall only be handled in storage facilities (or storage containers), the positron preparation room, and the PET procedure room.
(3) The partitions, etc., shall be shields sufficient to ensure that the effective dose on the outside of each will not be more than 1 millisievert per week, except for partitions, etc., in or outside of areas where no persons go.
(4) No platform for operating PET equipment or MRI equipment shall be present in the PET/MRI examination room.
(5) A dosimeter shall be required to check for radioisotope contamination, materials, devices, and cleaning equipment required for decontamination of radioisotopes, and a facility for changing clothes shall be available in the vicinity of the exit of the room where positron emission tomography radioisotopes are used.
(6) Cleaning equipment shall be available in the positron preparation room.
(7) The cleaning equipment specified in (5) and (6) above shall be connected to water discharge equipment.
(8) If any apparatus, such as a hood or glove box, for preventing the spread of gaseous radioisotopes or radioisotope-contaminated materials, is present in the positron preparation room, the apparatus shall be connected to an exhaust system.
(9) The PET/MRI operating room shall be located in a controlled area for radiation, and shall be a facility that meets the criteria for MRI equipment access-prohibited areas.

3. Safety Education and Training for Operators of Combined PET/MRI Systems

The manager of the hospital, etc., shall endeavor to secure medical safety by periodically implementing an education/training program for the medical radiology workers and MRI operators involved in the PET/MRI examination.

3.1 Safety education and training for persons engaged in the FDG-PET examination

Education/training for ensuring radiation protection and medical safety shall be provided for

medical radiology workers, etc., involved in the FDG-PET examination.
(1) Raising awareness of FDG-PET examination guidelines and operating procedures (reference 1)
(2) Prevention of radioactive contamination associated with the use of FDG chemicals, etc., and radioactive decontamination
(3) Radiation protection of medical radiology workers
(4) Radiation safety and radiation exposure reduction for caregivers, patients other than those receiving FDG-PET scans, and the general public

3.2 Safety education and training for persons engaged in the operation of MRI equipment
To ensure the safe and effective operation of MRI equipment, education and training shall be provided for MR equipment operators.
(1) Emergency care
(2) Access-prohibited area
(3) Emergency demagnetizing device
(4) Fire prevention measures
(5) Emergency measures to be taken in the event of a quench incident
Emergency measures to be taken in the event of quench incidents shall include detecting a quench incident. In preparation for quench events, especially in cases where the exhaust system for the superconducting magnet system has failed, drills must be implemented with top priority given to the rescue of patients, etc., and the “personal” safety and security of MRI operators, etc.

3.3 Safety education and training for persons engaged in the PET/MRI examination
Education and training concerning the safety and security of those using combined PET/MRI systems shall be provided to both medical radiology workers and MRI operators involved in the FDG-PET examination. In particular, for the rescue of patients, etc., receiving PET chemicals, it is necessary to fully implement radiation protection measures.

4. Emergency Action Plan in Preparation for Quench Events During Operation of Combined PET/MRI Systems
The facility containing the combined system is located in a controlled area for radiation protection, and the patients, etc., to be rescued are recipients of PET chemicals. Therefore, actions focusing on radiation safety are essential. Stated below are emergency actions to be taken to ensure the radiation safety of workers involved in the operation of combined PET/MRI systems.

(1) A layout of the PET/MRI operating room shall be provided and show the windows and evacuation routes that allow persons and exhaust gases to exit the room.
(2) A manual emergency switch shall be available to enable the staff to quickly transfer the patient lying on the scanning bed, and the staff shall be aware of its location.
(3) Emergency staff (e.g., ambulance team members, in-house fire extinguishing team, in-house and outside security personnel) shall be available and each shall understand his/her respective role.
(4) An explanation and relevant information shall be provided to the nearby fire station and police station (this must take place before onset of an actual emergency). The presence or absence of a magnetic field should be confirmed.
(5) Rescue work shall be done by at least two staff members.
(6) The staff involved in the operation of the equipment shall be trained for supervision during evacuation from the PET/MRI operating room and the rooms around it.
(7) The patient, etc., undergoing PET examination can be a source of radiation. Therefore, the rescued patient, etc., shall immediately be transferred to the PET waiting room and forced to stay there. Records concerning the rescued patient, etc., including the choice of PET chemical administered (type of radionuclide), dose of radioactivity (MBq), and time of his/her transfer from the PET/MRI examination room to the PET waiting room, shall be recorded for archival purposes.
(8) The staff shall not return to the PET/MRI examination room unless the situation normalizes, i.e., the sound is no longer heard and the normal view is restored. For safety's sake, all rooms shall have their windows and doors to the outside opened to maximize ventilation.

References

1. Guidelines for Safety Security in FDG-PET Examination (2005). Japanese Journal of Nuclear Medicine (Kaku Igaku) 2005; 42: 1–26.
2. Guidelines for PET Examination Using In-house-produced FDG (2nd Edition) (Japanese Society of Nuclear Medicine). Japanese Journal of Nuclear Medicine (Kaku Igaku) 2005;42: 1–22.
3. Guidelines for Imaging Techniques in FDG-PET Examination. Japanese Journal of Nuclear Medicine Technology (Kaku Igaku Gijutsu) 2007;27: 425–456.
4. ICRP. 1998 recommendations of the international commission on radiological protection. ICRP PUBLICATION 80. Annals of the ICRP; 1998. Elsevier Science Ltd, Oxford.
5. Guidelines Concerning the Use of FDG-PET for Cancer Screening. Japanese Journal of Nuclear Medicine (Kaku Igaku) 2007;44: 1–28.
6. National Council on Radiation Protection and Measurements. Limitations of exposure to ionizing radiation. National Council on Radiation Protection and Measurements; NCRP Report No. 116 1993.
7. Medical and Dental Guidance Notes: A good practice guide on all aspects of ionizing radiation protection in the clinical environment. IPEM, 2002.
8. Kangarlu A and Robitaille PML. Biological effects and health implications in magnetic resonance imaging. Concepts in Magnetic Resonance, 2000;12, 321–359.
9. Guidance for industry and FDA staff - Criteria for significant risk investigations of magnetic resonance diagnostic devices: U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. July 14, 2003.
10. Kanal E et al. American College of Radiology White Paper on MR Safety: 2004 update and revisions. AJR Am J Roentgenol 2004;182:1111–1114.
11. Shellock FG et al. MR procedures: biologic effects, safety, and patient care. Radiology 2004;232: 635–652.
12. Gowland PA et al. eds. Special issue: MR safety. J Magn Reson Imaging 26, Number 5, 2007.
13. Shellock FG. The reference manual for magnetic resonance safety, implants and devices: 2008 eds. Biomedical Research Publishing Group, Los Angeles.
14. JIS Z 4951:2012. Medical Electrical Equipment - Part 2-33: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis, Japanese Standards Association.

Acknowledgment

This work was supported by Japanese Radiologic Society (The President, Sachio Kuribayashi), Japanese Society of Nuclear Medicine (The President, Tomio Inoue), Japanese Society of Magnetic Resonance in Medicine (Director Representative, Mamoru Niitsu), Insurance Committee of Japanese Radiologic Society, PET・MRI Insurance Committee of Japanese Radiologic Society, and Health Insurance Committee of Japanese Society of Nuclear Medicine

This work was also supported in part by Grand-in-Aid for Research Foundation for Community Medicine, Japan. The authors also thank to SIEMENS Healthcare Japan K.K., GE Healthcare Japan Corporation, and Philips Electronics Japan, Ltd. for support and data handling.