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Current situation in Polish nuclear medicine and Polish example of model Nuclear Medicine Centre meeting European Union requirements

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Summary. Nuclear medicine is currently a well-established part of medicine. It is applied in many fields of clinical medicine and science like endocrinology, oncology, cardiology, molecular medicine and engineering, radiopharmacy, physics and information science. Due to its increasing importance and application, several regulation and supervision bodies have been founded to ensure safe usage of radiation and to improve diagnostic and therapeutic procedures. This article reviews the legal requirements of Polish law regarding a fully functional Nuclear Medicine Centre (NMC) and reports on the current situation of nuclear medicine in Poland. It also suggests a model project for NMCs compatible with Polish and European Union regulations.

Key words: radiological safety standards, nuclear medicine, model Nuclear Medicine Centre

«Situazione attuale della medicina nucleare polacca ed esempio polacco di modello di Centro di Medicina Nucleare conforme ai requisiti dell'Unione Europea»

Riassunto. La medicina nucleare è attualmente una branca consolidata della medicina. Molti ambiti della medicina clinica e di scienze vedono applicata la medicina nucleare, tra questi figurano: endocrinologia, oncologia, cardiologia, medicina molecolare ed ingegneristica, radiofarmacia, fisica e scienze informatiche. Data la rilevanza crescente e le numerose applicazioni in essere, sono stati istituiti alcuni enti regolatori e di supervisione per assicurare l'utilizzo sicuro delle radiazioni e il miglioramento delle procedure diagnostiche e terapeutiche. Il presente articolo, riassume i requisiti legali necessari secondo la legge Polacca all'interno di un Centro di Medina Nucleare (NMC) completamente funzionale, evidenziando l'attuale stato della medicina nucleare in Polonia. Si vuole inoltre proporre un modello progettuale per strutture NMC conformi alle normative della Polonia e dell'Unione Europea.

Parole chiave: standard di sicurezza radiologica, medicina nucleare, modello di Centro di Medicina Nucleare

Nuclear medicine decision-making bodies

In the pursuit of prolonged life spent in optimal physical form human beings have put to good use not only experience gained but also the newest inventions and discoveries. This statement also applies to the discovery of radioactivity in 1896 by Henri Becquerel. Popularisation of radioisotopes thanks to the Manhattan project since 1946 made that discovery even more potent.

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A hallmark of nuclear medicine is its interdisciplinary character such that it is hard to guess the true origin of this field. In a typical nuclear medicine centre (NMC) one can find not only medical doctors of various specialities, but also physicists, pharmacists, IT experts, molecular biologists and nuclear medicine technologists. The very term "nuclear medicine" dates back to year 1952 and derives from American literature (1).

Nowadays nuclear medicine is a widely acknowledged branch of medicine with its main application in diagnostics and treatment. Due to its relatively late emergence and the nature of the materials utilised, it is rigorously controlled and supervised in order to guarantee safety. Moreover, in parallel with this thorough control process, there have been constant improvements to diagnostic and treatment procedures (2).

In the European Union supervision and control of medical implementation of ionising radiation is performed by the European Atomic Energy Community (EURATOM). The main responsibility of this organisation is to establish general safety norms for employees and the rest of society in order to protect them from ionising radiation (EURATOM Council Directives 2013/51 and 2013/59). In Poland, supervision of the correct usage of nuclear energy is performed by the President of the National Atomic Energy Agency (PAA President) who is nominated by the Prime Minister. Any decision or regulation is made together with members of the Council for Nuclear Safety and Radiological Protection Affairs (regulated by the Minister of Environment from 03/11/2011) which is composed of prominent scientists and practitioners of nuclear medicine and atomic energy as well as government representatives. Medical utilisation of ionising radiation is controlled by the Health Ministry co-operating with the PAA President. Local supervision and execution of directives once passed, especially in the field of patient and medical staff radiological protection, are performed by the provincial inspectorate of sanitation and epidemiology (Atomic Law dated 29/11/2000).

Safety law and improvements to service quality are also shaped by government (National Centre for Radiologic Protection founded by a Ministry of Health act 10/03/2011) and non-government (Polish Society of Nuclear Medicine) organisations. Important organisations world-wide are: International Atomic Energy Agency (IAEA), International Commission on Radiation Units and Measurements (ICRU), International Radiation Protection Association (IRPA), Inter-Agency Committee on Radiation Safety (IACRS), European Association of Nuclear Medicine (EANM), International Commission on Radiological Protection (ICRP), and Society of Nuclear Medicine and Molecular Imaging (SNMMI).

Norms standardising NMCs

The main role of the NMC is to provide diagnostic and therapeutic services using radiopharmaceutical products by means of strictly controlled procedures. Each NMC has to comply with every regulation for healthcare centres imposed by the Ministry of Health in 10/11/2006, an act of parliament dated 30/08/1991 and a set of Ministry of Health and government acts specific to NMC.

No NMC can start operation until on approval by the PAA President. The minimum equipment and staff requirements for NMCs providing diagnostic and therapeutic (non-oncologic) services using radiopharmaceutical products are specified in a Health Ministry regulation dated 27/03/2008. According to this act, each unit providing such services should be equipped with at least one single-head scintillation camera and supporting equipment enabling basic internal tests to be performed. Each nuclear medicine centre has to employ at least one: medical doctor (MD) specialising in nuclear medicine, nuclear medicine technologist trained in the use of a scintillation camera, nurse, and medical physicist.

Oncological treatment using radiopharmaceutical products is regulated by another Health Ministry acts dated 22/12/2014 and 12/11/2015. This type of unit is required to have at least: one planar or rotational scintillation camera allowing full body examination, one detector of absolute radiopharmaceutical product activity , one surface contamination meter, one radiation dose meter, one flat panel radiation source for inner testing of scintillation cameras, other devices required for inner control of parameters, and additionally in case of treatment of thyroid cancer with use of Iodine-131 (^{131}I), a meter of ^{131}I thyroid content.

The minimal supporting equipment comprises: a radiochemical fume hood, personal protective equipment (PPE) against ionising radiation, a needle sheath protecting from exposure to β- and γ-radiation, collimators for the scintillation camera relevant to the type of radiopharmaceutical product used, phantoms for basic inner control of parameters of radiological devices. The unit has to be operated by at least one medical doctor specialising in nuclear medicine per 500 patients per annum, one nuclear medicine technologist per scintillation camera per shift, one specialist in medical physics per 1000 patients per annum.

Each NMC should have one preordained place for preparation of (*i*) radiopharmaceutical products, (*ii*) patient services, and, (*iii*) in case of stationary treatment, clinical procedures.

According to the Health Ministry regulation 21/08/2006 there should also be space designated for isotope laboratories of categories I, II and III meeting the requirements of Polish Atomic Law dated 29/11/2000 and the Council of Ministers regulation brought in on 12/07/2006.

The Health Ministry regulation on 21/08/2006 states that the surface of the scintillation camera room should not be smaller than 20 m^2 and the height at least 2.5 m. All rooms within an NMC have to be air-conditioned. The distance between the scintillation camera operator and patient during a procedure should be at least 1.5 m. The scintillation camera has to be installed in such a way that the patient may be accessed from at least two sides. The regulation further specifies that in a given room only one scintillation camera may be installed. There must not be any device unrelated to the scintillation camera or the procedure performed on a patient at any given time. If the NMC is also providing stationary therapy there is a requirement for additional diagnostic equipment, a consulting room, and rooms for (*i*) storage and reception of radiation sources, (*ii*) preparation and dosage of radiopharmaceutical products, (*iii*) hospitalisation of patients treated with ^{131}I in doses exceeding those allowed for ambulatory application, (*iv*) storage and collection of contaminated bedclothes, underwear and radioactive waste, (*v*) a changing room with storage of clothes, dosimetric gate, and shower cabin with washbasin, (*vi*) diagnostic equipment, (*vii*) a waiting room where patients are kept separate before and after delivery of radiopharmaceutical product, and (*viii*) a sanitation point equipped with liquid hand soap, disposable towels or hand dryer and disposable seat covers. Moreover, in hospitalisation of patients treated with ^{131}I, there should be only one patient per room.

According to the Health Ministry regulation of 10/11/2006, in every healthcare point there should be a room allocated for medical staff with access to sanitary facilities. The main entrance hall should contain an information point, space for wheelchairs and baby carriage, space for outer garments, and access to a water closet. There should also be at least one room for cleaning equipment as well as one for waste. For medical staff there should also be a sanitation and hygiene room fulfilling the requirements of work safety and hygiene. Diagnostic-procedure and consulting rooms should have a surface of at least 15 and 12 m^2 respectively. Units should also contain a backup water supply lasting for at least 12 hours' operation. The building should also be equipped with a remote energy generator with auto-start function covering at least 30% of peak demand, additional uninterruptable power supplies (UPS) with adequate power supply, and optional batteries.

An NMC has to obey radiological protection practice for both patients and personnel. It is also obliged to implement the standards of the International Standardisation Organisation (ISO). The practice consists of: (*i*) justification of referral for treatment and patient's exposure; (*ii*) optimisation of exposure, (*iii*) determination of reference levels, and (*iv*) implementation of a quality control process and continuous upgrade thereof. For medical personnel this means: (*i*) optimisation of exposure, (*ii*) implementation of limits on doses and usage, (*iii*) classification of personnel in order of annual reception of radiation, (*iv*) monitoring of the work environment, (*v*) utilisation of PPE. The NMC should also pay attention to improving the qualifications of its medical personnel (Health Ministry Regulations dated: 18/02/2011, 11/02/2011, 02/02/2011, 02/02/2007 and 01/12/2004; Regulations of the Ministry of Labour and Social Policy 29/11/2002 and 26/09/1997; Labour Code and Regulations of the Council of Ministers (3, 4).

Current situation of nuclear medicine in Poland

According to the report by the National Consultant for Nuclear Medicine, Prof. Leszek Krolicki, prepared for the Health Ministry in 2008, there were 252 medical doctors and amongst them 136 specialists working in NMCs in 2008 (1). Importantly, an increase in the number of nuclear medicine doctors was noted when compared to the year 2000, when there were only 125. The number of employees with higher education has also risen from 115 in the year 2000 to 170 in 2008 (1, 5, 6). Yearly, there are approximately 15 new nuclear medicine specialists trained. There was a total of 63 registered NMCs in Poland in 2008 (55 public and 8 private) compared to 51 in the year 2000. In 2000, NMCs were equipped with a total of 108 basic apparatuses enabling radioisotope diagnostic testing: 24 devices for thyroid scintigraphy, 65 single-head gamma cameras, 17 dual-head gamma cameras, 2 triple-head gamma cameras. This does not include PET-CT devices, as until 2007 there was only one device of this type working in Poland and that was in Bydgoszcz. Currently, there are 24 PET/CT and 1 PET/MR active scanners with an average of 1 scanner per 1.5 million people (7). The majority of radiopharmaceuticals used are from National Centre for Nuclear Research, Radioisotope Centre (POLATOM).During the next eight years there was a decrease in the number of radioisotope diagnostic devices, the total being 103 in 2008. It must be noted that most of them did not meet the requirements of modern nuclear medicine as some of them had been functioning for the last 24 or in some cases even 32 years. Despite the drop in the number of those devices, the overall amount of diagnostic (117,435 in 2000 and 156,214 in 2008) and therapeutic (12,379 in the year 2000 and 18,105 in 2008) services provided increased (8). However, the total number of procedures is still unsatisfactory as the ultimate goal is to reach 700,000 procedures a year. This mediocre situation, according to Prof. Krolicki, is a result of a small number of specialists and an undeveloped nuclear medicine infrastructure (5). As of 13th November 2015, the overall number of units providing medical specialty and residency in nuclear medicine were 28 and 13, respectively (Figure 1). Physicians specialising in nuclear medicine are now trained according to the updated syllabus meeting the requirements of the European Union of Medical Specialists (UEMS) (5, 9). Importantly, the ongoing rapid development of imaging, radiopharmaceuticals, and instrumentation techniques poses a challenge for frequent and comprehensive updates in the training programmes in order to provide optimal healthcare value (10).Units providing this opportunity should be equipped at least with one gamma camera enabling stationary, dynamic and SPECT testing, and provide basic radioisotope services (including SPECT) and radioisotope therapy (The Speaker of the Parliament act, 23/12/2011). The unit should also perform a sufficient number of procedures to enable physicians being trained to complete their specialisation. Specialisation unit should also provide access to libraries with nuclear medicine textbooks and access to medical journals, as well as organising regular meetings of clinicians in order to discuss recent progress in the literature, and to present their recent diagnostic work and clinical cases (interclinical meetings would be favoured).

A nuclear medicine centre project

The advancement of knowledge in fields like immunology, oncology, and cellular and molecular biology has accelerated the development of new medical technology resulting in enhanced quality diagnostic images and oncological treatment on a molecular level (11-15). It follows that modern NMC should have a solid scientific and didactic base enabling those technologies to be implemented. Moreover, due to the increase in demand for nuclear medicine experts, new specialists should also be trained (5). NMCs are also required to meet dosimetric standards and thus emphasis should be placed on radiation monitoring, e.g. whole-body dosimetry or cumulative radiation dose (16-19).

Currently, any high-standard NMC characterised by high patient throughput, adaptation for scientific research and tuition and providing high quality services, needs to be equipped with at least: two dual-head gamma cameras, one SPECT gamma camera, two single-head gamma cameras, a high-standard radiochemical laboratory, and a set of remote and stationary dosimetric devices and personal protection shields. In this paper we present a model for NMCs fulfilling modern

Figure 1. Current distribution of nuclear medicine training centres in Poland. Number of centres offering medical residency in nuclear medicine are shown as black digits on white background. Number of centres offering medical specialty in nuclear medicine are shown in white digits on black background. Numbers in brackets stand for the number of positions offered.Based on the Centre for Postgraduate Medical Education data for 13.11.2015 (http://www.cmkp.edu.pl/). Since 04.04.2016 the number of medical specialty positions in Wroclaw has increased to 6.

standards and current legal requirements (Figures 2 and 3). The NMC building and every device installed have to be in agreement with EU harmonised standards developed by the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI).

General notes

In a model NMC the patient's contact with medical personnel should be reduced to a minimum amount of time. Straight after delivery of the radiopharmaceutical product, the only time when the patient is in close proximity with staff should be during the test procedure. NMC units are equipped with sewage systems meeting parliamentary regulation 03/12/2002 on radioactive waste and spent nuclear fuel (8, 20). Wall thickness is described by document PN/86J/80001. Floors should be made of materials enabling fast disinfection and cleaning and the wall-floor junction should be made without any gaps or slits. Every room within the NMC is to be cleaned and monitored densitometrically on a daily basis. Door through which patients are to be transported on hospital beds should be at least 1.1 m wide. NMC doors are opened with staff's magnetic ID

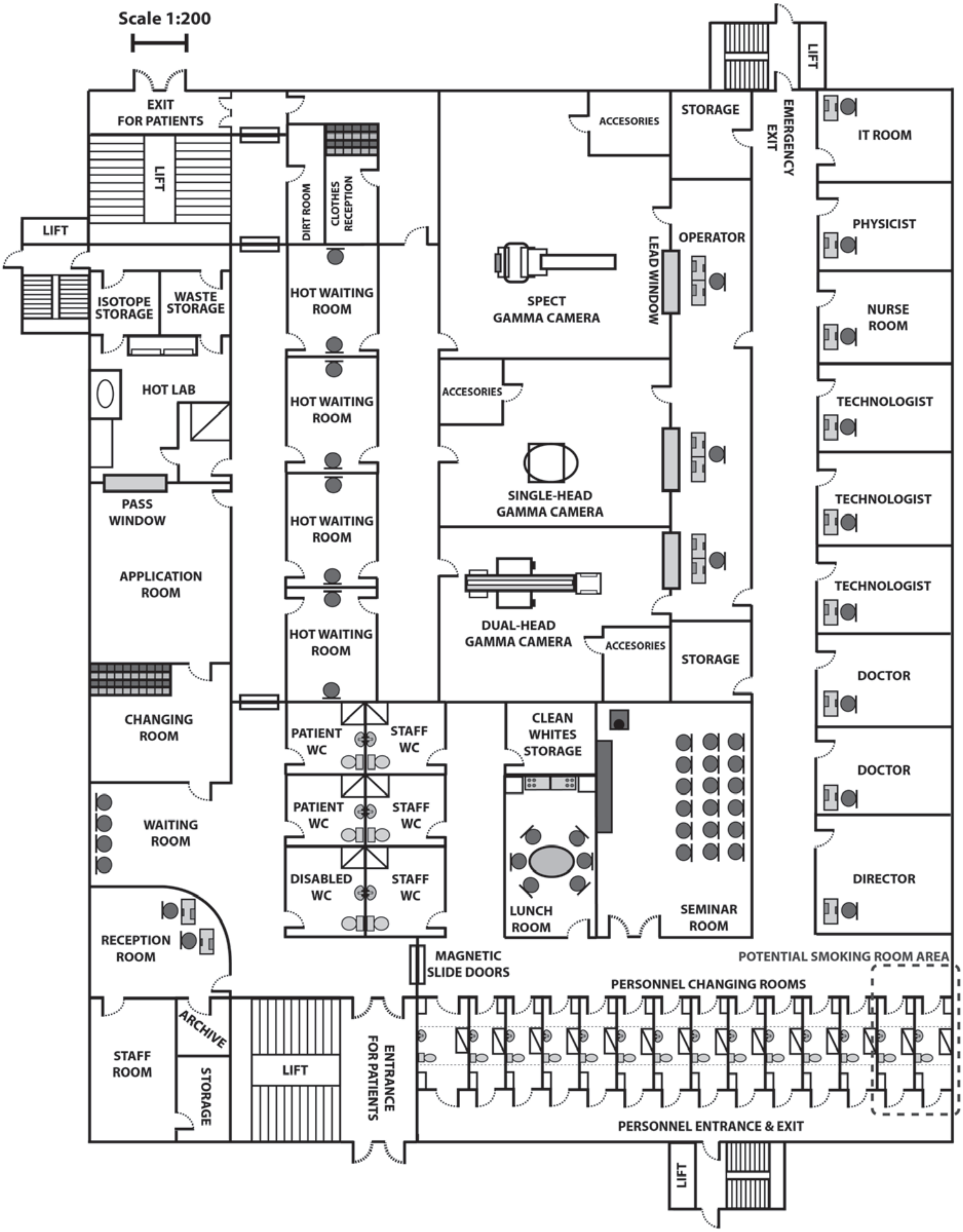

Figure 2. NMC - diagnostic (ground) floor.

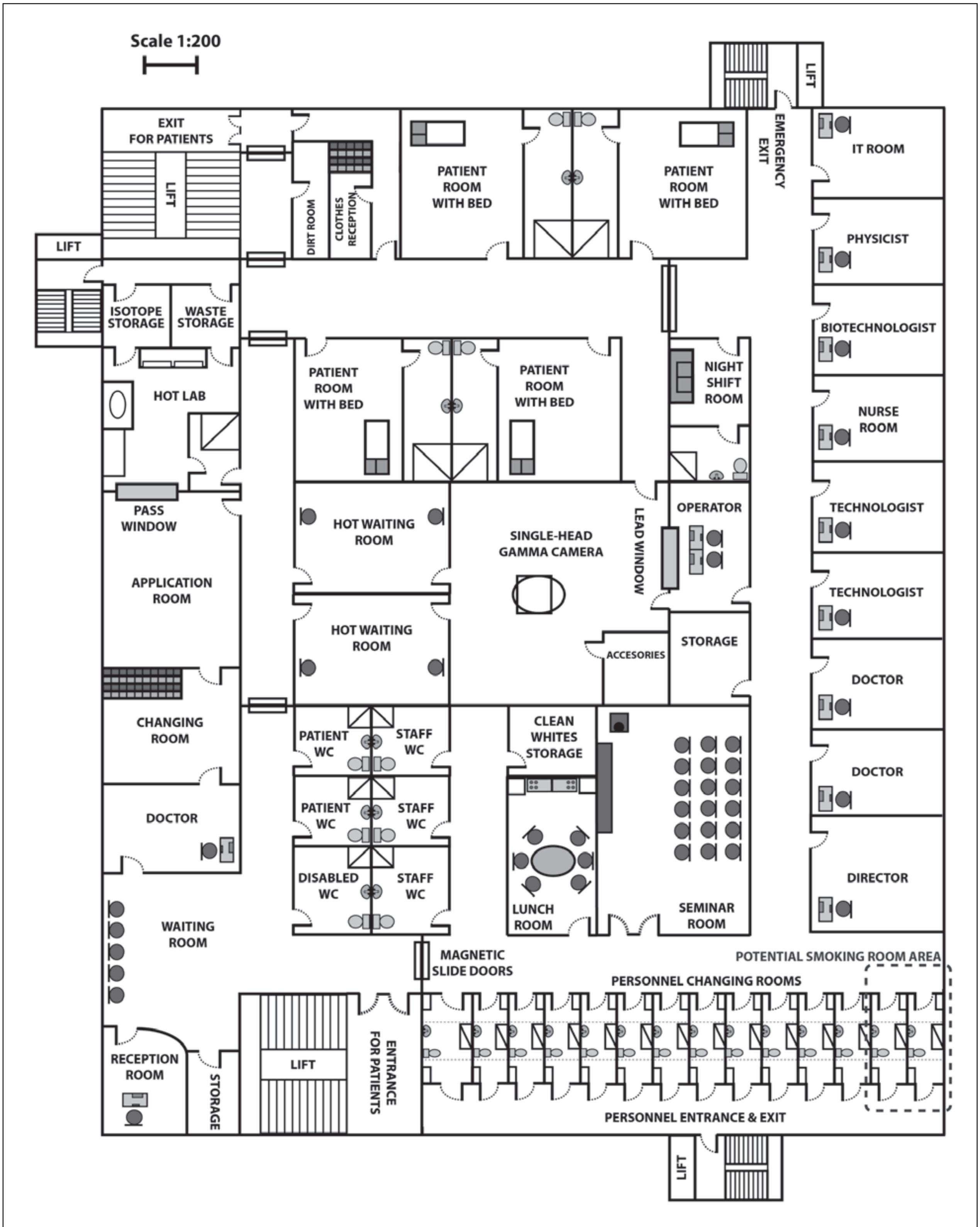

Figure 3. NMC - therapy floor (first).

cards. Patient rooms on the therapy floor are of single room type (in exceptional situations the room could be furnished with an extra bed at a minimum distance of 1.5 m) suitable for clinical procedures. Patient rooms are also equipped with tablets having access to the Internet. Personnel rooms are equipped with multimedia with a connection to the central NMC network and with access to the Internet. Every computer in the unit will have access to all on-line journals specialising in radiology and nuclear medicine. Staff changing rooms are equipped with space for footwear, a shower cabin, outer garment cupboard, washbasin, a contact-free liquid disinfectant container, regular liquid soap, disposable towels, a locked container for dirty clothes, and a cupboard for professional clothes.

Potential smoking room

The decision whether there should be smoking rooms is left to the NMC owner (Ministry of Labour and Social Policy regulation, 04/08/2011). Taking into account the diminished stress level of patient smokers and the verdict of the Supreme Administrative Court in Łódź on 24/01/2003 dealing with discrimination against smoking employees, the designation of a smoking room or area is justified, although arguable. In order not to expose non-smoking people to tobacco smoke, a smoking room should be a designated separate space well isolated from other rooms and passageways. It should have an active air exchange system allowing ten-fold air exchange over a one hour period. During peak hours, each smoker using the smoking room should have a minimum of 0.1 m^2 floor surface. The surface of each smoking room must not be smaller than 4 m^2. It should also have enough ash trays (Act of Parliament, 08/04/2010 and regulations of the Ministry of Labour and Social Policy). Patient rooms with bed on a therapy floor must comply with these requirements. Potential smoking rooms for employees are represented by a brown dashed line.

Patient movementson the diagnostic (ground) floor of an NMC

On entering the NMC, the patient is expected to approach the reception point in order to be informed of further directions and procedures. Next, the patient should stay in the waiting room area and wait until called to the changing room. This is where patients leave their outer garments and shoes (which are transported through an automated system to the collection point) and receives disposable clothes compatible with NMC standards. Then the patient is shown to the application room where injection of the radiopharmaceutical product takes place. Straight after injection, the patient enters one of four hot waiting rooms and awaits a call to a specific room (1, 2, or 3) with either a single-head, dual-head or SPECT gamma camera where the main medical procedure takes place. After the procedure the patient is shown to the clothes and shoes collection point and then to the exit.

Patient movements on the therapy (first) floor of an NMC

On entering the first floor of the NMC, the patient is expected to approach the reception point in order to be given further directions and procedures. Next, he/she is admitted to the consulting room, where a doctor explains the details of the medical procedure in question. Then patient heads towards the changing room and leaves his/her outer garments and shoes (which are transported by an automated system to the collection point) and receives disposable clothes compatible with NMC standards. The changing room is where patients waiting for a call to the application room. Having received the injection with radiopharmaceutical product, patients are either guided to one of four patient rooms, or to one of the two heated waiting rooms from which they will later proceed to the diagnostic room. After the procedure, patients are expected to head for of the patient rooms to be hospitalised for the required time according to the treatment provided. Finally, on receiving the doctor's approval, the patient is discharged from the NMC, collects his/her clothes and shoes at the collection point and leaves the building.

Movements of staff within an NMC

On entering the NMC through the staff entrance, employees head for one of the staff changing rooms. They take all their clothes off, put on flip-flops and proceed to the sanitation zone within the changing room. There they put on clothes and shoes fulfilling the NMC's standards. This is also where the dirty underwear is disposed of after the shift. The NMC is also equipped with a social room where employees can consume food (supplied by a chosen catering company) and cold or hot beverages. There is also a seminar/multimedia room with an electronic library and Internet access. The therapy floor is additionally equipped with a night-shift room. There are three water closets with a shower and washbasin. Staff movements are similar on both floors.

Conclusions

Medicine is constantly evolving with enhanced and innovative solutions requiring improvement of norms and standards of diagnostic and therapeutic procedures. Upgrades to staff qualifications, modernisation of radiation detectors, novel software, personal protection shields made of modern materials, new generation radiopharmaceutical products (lowering the patient and staff health risk) are all features that augment the demands on a nuclear medicine centre. Enlarged rooms limit staff and patient exposure to ionising radiation while improving comfort at work. Already existing units will face a problem of meeting space and infrastructure requirements and potential renovation might turn out to be expensive. Thus newly-built units may in future become centres of nuclear medicine meeting the more rigorous standards.

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