Aim The aim of this project is to define technical and professional standards of clinical practice in nuclear medicine that, if universally applied, would make it possible to assure any stakeholder that the quality of diagnostic imaging, therapy, radiochemistry and radiopharmacy is verified and homogeneous across the nation's different centers. These standards should specifically address issues relating to safety, both of patients undergoing diagnostic imaging or therapy and of personnel. The standards should be implemented on a voluntary basis and may be pursued by any nuclear medicine facility.

Materials and methods A series of general rules and principles was established: (a) the accreditation model must comply with the ISO9001 standard and be based on the Plan-Do-Check-Act (PDCA) method; (b) the model should, in an achievable and gradual manner, promote the highest quality of care in nuclear medicine practice, defining a minimum level of quality that should be met by all centers (standard level) and a higher level aimed specifically at centers wanting to be awarded accreditation of excellence; (c) the standards of practice must be developed within the profession; (d) the nuclear medicine community will be encouraged to adopt the standards voluntarily; (e) a certification body responsible for the certification process should be identified.

Results This endeavor has resulted in the creation of a set of standards which provide a robust template for quality care and risk management in nuclear medicine practice. The accreditation model covers document management (with a view to defining a common template for reporting the results of examinations), resource management, service supply, and appropriateness of diagnostic imaging and therapy. Quality indicators have been defined, both for the entry level and for the level of excellence. Bureau Veritas, a global certification leader that offers a broad range of customized certification and audit services in the health and safety field, has been identified as the certification body that will assist AIMN in the audit process. Two nuclear medicine centers in Italy have already been audited and found to comply with the proposed accreditation model. Ten more centers have been selected by the AIMN board, and are expected to be audited in the next few months. The results of these audits will be presented at the XI AIMN congress.

223 Application of lean thinking for optimization of the Department of Nuclear Medicine at the INM Neuromed

L. Armisì, F. Sebastiano, F. Calabria, O. Schillaci

1Clinical Engineering Service, Technical Division, Istituto Neurologico Mediterraneo Neuromed, Pozzilli (IS), Italy
2Department of Nuclear Medicine, Istituto Neurologico Mediterraneo Neuromed, Pozzilli (IS), Italy
3Department of Biopathology and Diagnostic Imaging, University of Tor Vergata, Roma, Italy

Objective Starting from the need to meet the requirements of good manufacturing practice of radiopharmaceuticals (GMP), the processes in place at the Department of Nuclear Medicine (NM) at the Istituto Neurologico Mediterraneo Neuromed were revised, with the aims of: optimizing the operating procedures, in reference to clinical risk management and health worker safety; ensuring compliance of the NM department with GMP; reducing the waiting list for PET/CT examinations; reducing the costs related to execution of tests. The multidisciplinary team responsible for the project (made up of scientific-academic representatives, nuclear physicians, medical radiation health technicians, clinical engineers) focused mainly on the procedures of molecular imaging, characterized by greater criticalities and areas for improvement, leaving, as a first step, SPECT procedures.

Methods The project is based on the principles of lean thinking, a management technique created in the industrial sector and designed to minimize waste and achieve maximum control of the production process. The principal steps in the project were: detailed mapping of the processes and procedures (Current State Map) applied in the NM department; identification of the main elements of waste, inefficiency and non-compliance with statutory requirements and scientific good practices; design of appropriate corrective and improvement actions and foreshadowing of the future ideal state (Future State Map); definition of a plan for the implementation of these actions; verification of the results, review of the action planning and objectives. The following corrective and improvement actions were identified and implemented: provision of the NM department with two administrative assistants to carry out critical tasks such as booking of tests, verification of patient satisfaction of the minimum requirements for the NM test, management of clinical records; review of supply procedures (orders, timing, storage and order) of radiopharmaceuticals; acquisition of equipment necessary for the completion of the radiopharmacy; adjustment of the architectural layout of the NM department, to clearly distinguish the reporting room, exam acquisition room, administration area, radiopharmacy, filters, quality control room; structuring of a Quality Management System (QMS) for the entire NM department, covering all aspects related to the clinical activities, with particular attention to the processes of preparation of radiopharmaceuticals, based on the GMP requirements.

Results After a trial period of 6 months, in comparison with the same period the previous year, the following results were obtained: an about...
12% increase in tests carried out; an about 23% reduction of the quantity of radiopharmaceutical orders; an about 40% reduction of the maximum activity of the source handled by staff; an about 46% reduction of canceled tests; adaptation of the department to the GMP; better job quality, as perceived by medical and paramedical staff of the NM department. The application of the QMS and lean thinking therefore represented the basis for a process of continuous improvement of the NM department, with the aim of better achieving the clinical, legislative and directional goals.

224 Economic impact evaluation of the application of the rules on good radiopharmaceutical preparation

F. Ria¹, E. Di Domenico², C. Tafuri², G. Pedrinelli², G. Chitti², P. Gandolfi¹, S. Papa³

¹Specialization School in Medical Physics, ²Quality Department, ³Nuclear Medicine Service, ⁴Diagnostic Imaging Department, CDI Centro Diagnostico Italiano S. P. A., Milan, Italy

Application of the rules on good preparation of radiopharmaceuticals in nuclear medicine (NBP) as stipulated by Italian ministerial decree of 30/03/2005, besides being obligatory, offers an opportunity for achieving better management of the risks associated with the use of radiopharmaceuticals, improving their impact and guaranteeing greater safety for patients, personnel and sanitary organizations. Positive effects have been obtained, especially, in terms of greater detectability of potential damage to the health of the patient as a result of the administration of unnecessary doses and drugs not guaranteeing the necessary standards of sterility and ariogenicity (radionuclidic purity and radiochemistry purity). Greater detectability and control of the critical elements mentioned above have made it possible to greatly reduce risks and/or potential consequential damage, as described by a risk analysis on the introduced change.

It is obvious the positive return for organizations, in facing a smaller number of legal arguments, the majority due to the traceability of the whole process, a standardization of the diagnostic investigation further to a great overburdened personnel. This process has a cost that, as it regards structures and equipment, can be previously analytically valued. Conversely, before the real implementation of the quality system, it is more difficult to provide a reliable assessment of the economic impact of some activities, such as the purchase of the necessary chemical reagents to the quality controls, the training of the personnel, the necessary man-hours for performing the quality controls, the drawing up of the relative forms and the possible expenditure of drugs not complying to the specific applications.

The aim of this study is to provide, on the basis of a first period of application of NBP in a department of Nuclear Medicine, a representation of all the necessary costs with the purpose of guaranteeing greater quality of the radiopharmaceuticals and the positive impact to the patient and the sanitary organization on the risk evaluation.

The related data can represent a guideline for structures that must cross similar experiences. They will highlight the real costs involved in achieving compliance with the best practice, comparing them to the overall management costs of a Nuclear Medicine department, thereby offering a tool that can facilitate a more punctual valuation of economic impact. Moreover, they will also underline the incidence on the business cost of the single performance, following the introduction of a quality system.

225 Risk analysis in a Nuclear Medicine Unit

M. Muratori¹, D. Maranzana¹, O. Gandini¹, G. Cuccu¹, A. Muni¹, H. Rouhanifar¹, M. Sumatra¹, L. Tommasi¹, D. Valentini², M. Zanaga¹, O. Testori¹

¹Nuclear Medicine Unit, SS. Antonio e Biagio Hospital, Alessandria, Italy ²Health Physics Unit, SS. Antonio e Biagio Hospital, Alessandria, Italy

Aim The aims of this work were the implementation of an incident reporting system in the Nuclear Medicine Unit of Alessandria Hospital and its permanent inclusion in the hospital’s quality system. The system will meet the patients’ health needs and lead to health services of verifiable quality.

Materials and methods 1- Creation of the incident reporting form: a questionnaire was given to the nuclear medicine staff, asking them to indicate incidents and near misses in the past 5 years. 2- Incident categories: Five incident categories were detected and identified by the working area in which the incidents happened: administrative, radiopharmacy, administration room, imaging (examination) area, reporting area. These areas correspond to well-defined phases in the diagnostic pathway. 3- Filling in, collecting and analyzing. The forms were available for the staff in each working area and were voluntarily filled in from July 2011 to July 2012.

Results Ninety-six forms were collected and 121 events or near misses emerged. The analysis highlighted the working areas and phases requiring most attention and consequently allowed appropriate corrective actions to be taken.

Areas and activities The reported events in the different areas occurred in the following proportions: administrative (16.5%), radiopharmacy (32.2%), radiopharmaceutical administration room (24%), examination area (20.7%), reporting area and other activities (6.6%).

Causes Inaccuracies – meaning deviations from the proper performance of a procedure – were the prevailing causes (41.3%). Then came malfunctioning of devices (35.5%), omissions – meaning failure to deliver a planned health service (17.4%) –, delays with respect to scheduled procedure performance times (3.3%), and others (mixed) (2.5%).

Factors Human errors were the prevailing factors (36.8%), followed by organizational errors (23.6%), patient factors (18.4%), and finally technological factors (21.2%).

Conclusions The incident reporting system allowed us to categorize the systematic bias, which otherwise would have been reported as sporadic. The implementation of this system has helped to change the cultural mindset of the staff who are now motivated to “learn from mistakes”. The reporting of incidents was largely accurate, even though in our opinion there is a tendency not to report one’s own mistakes, while it is easier to report mistakes due to technological problems or to other professionals. For the most significant events, some corrective actions were taken: revision of the Quality Manual, the reporting system, and the Procedure Handbook. This survey will be repeated after a year, in order to evaluate the effectiveness of the corrective measures.

226 Laws, rules and quality patterns: encirclement, opportunity or “conditio sine qua non”

G. Chitti², E. Di Domenico¹, C. Tafuri¹, G. Pedrinelli¹, F. Ria², P. Gandolfi¹, S. Papa³

¹Quality Department, ²Specialization School in Medical Physics, ³Nuclear Medicine Service, ⁴Diagnostic Imaging Department, CDI Centro Diagnostico Italiano S. P. A., Milan, Italy

National legislation on radiation protection, regional legislation on the accreditation of health care facilities, and standards and quality certifi-