Equipment Introduction

Reading guide

The primary aim of the following chapters on nuclear medicine equipment is to ensure that patient care can be carried out responsibly. It provides basic descriptions of quality controls to identify equipment faults in time. Instructions are given as to how to perform quality controls, how often to perform these tests and how to interpret the results. Medical physicists who have the ability and competence in nuclear medicine equipment should be able to apply these recommendations in practice. Many tests can be translated to local protocols that can be carried out by nuclear medicine technologists under supervision of a medical physicist. In some cases, additional literature might be needed to successfully perform the tests, such as the publications by the National Electrical Manufacturers Association (NEMA).

These recommendations deal with the following nuclear medicine equipment or items:

- Gamma camera
- PET-CT scanner
- Dose calibrator
- Radiation monitors
- Personal dosimeters
- Semiconductor detector
- Gamma sample changer
- Probes
- Medical software
- Co-registration in hybrid imaging devices
- PET-CT in radiation treatment planning

In the field of nuclear medicine it is becoming more common practice to use radiology equipment either in a stand-alone situation or in a combination with nuclear medicine equipment, e.g. as is the case for PET-CT, SPECT-CT and PET-MRI devices. However, quality control of radiology equipment is only described limitedly in these recommendations, as these are developed and improved in a dedicated working group of the Dutch Association of Medical Physics (NVKF). The basics of these protocols are similar to the protocols for nuclear medicine equipment: they are also intended as a practical guideline for medical physicists who perform measurements on diagnostic equipment.

General Recommendations on Equipment Checks

1. Introduction

Many different tests are described in the literature for checking equipment. Unless a careful selection is made from these, the equipment may end up being withdrawn from patient care unnecessarily and for an irresponsibly long period of time. Apart from the actual tests, the frequency with which they are carried out and the thresholds for action need to be chosen carefully. The objective of the quality checks set out in the following chapters is to ensure that patient care can be carried out responsibly and that clinically relevant equipment faults are identified on time.

2. Selection protocols

Quality checks of medical equipment are carried out at all phases of the lifespan of the equipment: prior to delivery, after installation or relocation ("reacceptance"), during the clinical use phase ("regular or frequent quality control (QC)"), and also after maintenance of the equipment. Specifically, acceptance checks are designed to determine whether the equipment meets the factory specifications. Therefore, when drawing up the protocols, they have been based, wherever possible, on available international protocols such as the protocols of the NEMA (National Electrical Manufacturers Association), the IEC (International Electrical Commission) and the IAEA (International Atomic Energy Agency). A disadvantage of these protocols is that quite frequently they are not easy to perform and they sometimes require very specific (and expensive) devices. One possibility is to have these checks performed, under supervision, on delivery by the manufacturer. In addition, sometimes such a complicated check can be modified in such a way that it becomes easy to perform and the result can be used as a baseline. Moreover, the result obtained may also be comparable, within limits, to the result that would have been reached using the original protocol. With older equipment, an evaluation must be made as to whether the factory specifications are still a sufficient guarantee of proper functioning. During regular QC, the tests in these recommendations must guarantee that problems that occur relatively frequently are detected on time. The fundamental principle here is that the equipment must be calibrated as prescribed by the manufacturer. The manufacturer's specifications take precedence over these recommendations. Typically, the method of carrying out the checks prescribed by the manufacturer will deviate (somewhat) from what is described in these recommendations, but if the manufacturer prescribes a sufficient frequency of testing, it will generally not be necessary to perform the associated test from these recommendations (see Section 3).

Four criteria have been used in selecting the tests:

a. *The premise is the alert professional user.*
   During normal use of the equipment, the occurrence of some (sporadic) problems will be visibly evident. While this may imply that the investigation must be repeated, there is no risk of incorrect or missed diagnoses. The quality control program is designed to detect precisely those changes that take place so slowly that they are invisible to the alert user before the quality of the investigation becomes unacceptably compromised. Only where a problem is indeed plainly visible but also occurs frequently can it be justified to test for it specifically (see criterion c).

b. *Quality assurance is directed at concrete test results.*
The result of a test (image or number) should in principle be compared to factory specifications or a baseline value. This comparison is only possible if a fundamental rejection criterion is available (see Section 4). Moreover, if a threshold for action is exceeded, then action must follow. If these conditions are not met, a test has no effect and may just as well have been omitted. Exceptionally, there are some tests which, rather than having to meet a certain specification, aim to characterize relevant clinical properties of the equipment. The results of these tests, which are usually only carried out during acceptance, must be made known to the user.

c. *The cost-benefit aspect is taken into account.*
Considering costs, attention has to be paid to:
- the time during which the equipment is not available
- the effort by the personnel
- the costs of phantoms, sources and isotopes
- the radiation exposure to the personnel

The benefits are determined by:
- the chance that a test will reveal a certain fault
- the chance that a fault occurs in clinical practice
- the consequences of such a fault if not detected in time (missed or wrong diagnoses are a serious consequence, repetition of the investigation is a less serious consequence)

d. *Optimal use of sensitive or specific tests*
A sensitivity test has a high negative predictive value (NPV): if the test result does not deviate from the baseline value, there is little chance that something is wrong. When a result does deviate, however, it is not necessarily immediately clear what has caused the deviation. Often, all or a large portion of the component parts of the instrument are tested at the same time. On the other hand, a specific test is valuable in identifying the exact cause of faults; if there is no anomalous result, anything could still be wrong with the equipment. In this case, the test often focuses on just one specific part or aspect of the device. Frequent checks should therefore preferably be sensitive, whilst specific tests can then accelerate the detection of the cause of a problem. Specific tests are performed mainly during acceptance so a baseline is available and the test may be repeated if there are problems.

3. Frequency

When a fixed frequency is chosen a priori, this can result in either too little testing, with a high probability of equipment not being in proper condition, or in unnecessary work and removal of equipment from patient care if the test frequency is too high. The frequency of testing should be adapted to the characteristics of the equipment and the circumstances of use. Moreover, just as with the selection of the checks, the cost benefit aspects should be taken into account (see Section 2c).

After installation, acceptance tests should be performed to determine whether the equipment meets the manufacturer's specifications and to obtain baseline values. The acceptance tests should (mostly) also be performed after very substantial maintenance, relocation, major hardware upgrades and/or if there are specific problems. Some of these tests also need to be repeated after less substantial maintenance. In the latter cases, they

are also called reacceptance tests, performance tests, reference tests or release tests. In addition there are checks (generally sensitive tests) that must be performed frequently. The frequency of these checks should be determined in an adaptive manner. After acceptance, tests are initially carried out with a high frequency. If, after some time, no deviation and no trend are found that will quickly lead to action thresholds being exceeded, the testing frequency can be lowered. On finding a deviation, the trend determines whether the frequency needs to be adjusted: where there is a sudden unexpected deviation, it is prudent to increase the frequency again, but if exceeding the threshold was already expected on the basis of the trend, this will not be necessary. Ultimately, all of this should lead to an optimal frequency. Again, the cost-benefit aspect must be taken into consideration. When the costs are low (test is very simple) or the benefits are high (major consequences of a possible fault), a test should be performed relatively frequently. However, in practice, tests may sometimes be carried out "too often" (where deviations are "never" found). Eventually they may end up no longer being performed. The best guarantee that tests continue to be repeated is by fitting them into a general maintenance routine, for example daily or weekly.

Usually, there is a minimum justifiable frequency. Tests will often need to be repeated after (major) maintenance. With annual maintenance, this amounts to an annual test, but some equipment has a shorter than annual servicing interval. Again, experience shows that isolated low-frequency tests cease to be carried out over time. Fitting them into a general maintenance routine offers the best guarantee that tests continue to be repeated. This may mean that tests are performed more often than is strictly necessary. If, during maintenance, a (major) adjustment to a system is made, it may be necessary to perform checks both before and after carrying out maintenance. If tests are only done after maintenance, deterioration of a system can go unnoticed.

In some cases it is necessary to do checks after switching on the equipment, as is the case with mobile devices where the risk of faults after a move is relatively high, and on recommissioning equipment after a power failure where the shut-down did not take place carefully.

These recommendations for checks are based on the situation where there is a one-time or at most occasional adjustment. Occasionally, a manufacturer prescribes very frequent adjustment. Without insight into the intermediate stability, this can lead to a false sense of security. It is also not always clear whether the time (and possibly also the radiation exposure) spent on these frequent adjustments is justified. It is recommended to check for stable behaviour in any event and, if necessary, consult with the manufacturer on adapting the procedures.

4. Thresholds for action

The test protocols available, such as the NEMA protocols, do define the measurement and analysis methods, but, as a general rule, make no mention of any (well-founded) action thresholds. On the other hand, factory specifications are not always available for all relevant parameters.

The point of departure is the equipment after purchase, including any available specifications. It is assumed that during the purchase process, the equipment is adjusted for its intended use. In many cases it will be a matter of compromise between the various specifications. Consequently, it is generally not possible to specify absolute action

thresholds, only the factory specifications can be checked.
It is therefore important to come to an agreement with the manufacturer, possibly even during the purchasing process, about the specifications to be checked and their acceptance values. Performing a test only makes sense if an absolute threshold for action and/or specifications for the equipment are available. If both are missing, there is no sense in carrying out the test.
Only in exceptional cases can action thresholds be determined more or less objectively from "first principles". Usually, just as when selecting checks, a balanced choice will need to be made, taking into account the cost-benefit aspects (just as in Section 2c). When the action threshold is correctly determined, no defects will normally be observed clinically; furthermore, the equipment will not be unnecessarily decommissioned (which can happen, for example, if the only aim would be to achieve the best technically feasible result). The determination of this balance is based on experience and consultation. In some cases, if an action threshold is exceeded, it is still possible for the equipment to be used within limitations (only for certain applications or with adjusted protocols).