Introduction to Suspension Levels: Nuclear Medicine

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Introduction to Suspension Levels: Nuclear Medicine

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Background

EU RP91

Now it is 19 pages long

8. NUCLEAR MEDICINE

The criteria given here have been chosen as ones to tests that can fairly easily be done on a regular basis in departments of nuclear medicine. If the criteria are not achieved this should be taken as an indication of the used to undertake further investigations to establish the causes and to help decide on remedial action. The criteria for gamma camera for planar and SPECT use and isotope calibrator are derived from IPEM Report 65 (IPSM, 1992).

Gamma camera (high resolution collimator - $^{99m}$Tc)

Uniformity

- The variation should be less than $\pm 10\%$ within used field. The test should be performed with and without collimator and at a specified energy windows ($E \pm 10\%$).

Sensitivity

- The sensitivity (ability to detect the gamma rays emitted from a radioactive source in cps/MBq) should differ less than 20% from baseline value.

Centre of rotation (SPECT)

- The deviation of the centre of rotation should be stable within half a pixel.

Multi-headed camera

Sensitivity

- Differences in sensitivity between any of the heads should be less than 10%.

Geometry

- Pixel by pixel correspondence of opposed views should be within a half a pixel.

Isotope calibrator

Linearity

- Linearity should be less than $\pm 5\%$ over the range of activities used.

Reproducibility

- The reproducibility should be less than $\pm 5\%$.

Accuracy

- The instrument accuracy should be less than 5% for gamma emitters of energy greater than 100 keV, and less than 10% for beta emitters and low energy gamma emitters.
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Background
The development and review process has involved a wide range of individuals and organizations, including experts from relevant professions, professional bodies, industry, standards organizations and relevant international organizations.

The comments received from the public consultation were analysed and taken into consideration in the final draft version of the document which is the subject of this Workshop.

In the same way, the conclusions of the Workshop will be taken into consideration in preparing the final document for submission to the European Commission.
Introduction to Suspension Levels: Nuclear Medicine

Background

In total 129 comments were received from the public consultation process regarding the Nuclear Medicine section. 

Six were general comments relating to the whole section.

The remaining 123 comments concern specific areas of the section.

Most of them covered the same issues but were submitted by different organisations or individuals.

More that 95% of the received comments were constructive and were accepted partially or in total.
Introduction to Suspension Levels: Nuclear Medicine

Background
All the comments were reviewed and compiled in table format together with the recommendations of the reviewing team.
The tables from all the sections will be submitted to the European Commission as part of the final project report.

Extract from the Nuclear Medicine section table

<table>
<thead>
<tr>
<th>No.</th>
<th>Code</th>
<th>Page</th>
<th>Line</th>
<th>Proposal</th>
<th>Reason</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>114</td>
<td>I</td>
<td>65</td>
<td>15</td>
<td>Add some sentences: Parameters depending on reconstruction settings should be evaluated with the manufacturers’ recommended settings for clinical applications (filters and convergence). This will guarantee that the parameters reflect image quality in practice – beyond being basic acceptance criteria.</td>
<td>A problem with some of the parameters is (e.g. spatial resolution) is that we don’t say anything about reconstruction filters and convergence, i.e. the parameters provided are really basic acceptance criteria and don’t say anything on the quality of the scans in practice.</td>
<td>Accepted. After line 15 on page 65 add “Parameters depending on reconstruction settings should be evaluated with the manufacturers’ recommended settings for clinical applications (filters and convergence). This will guarantee that the parameters reflect image quality in practice.”</td>
</tr>
<tr>
<td>115</td>
<td>AAA</td>
<td>66-67</td>
<td>Section 3.5</td>
<td>In Section 3.5.3 a new test has been proposed for testing the alignment of a hybrid system. While woefully short on details as to what pixel size (CT pixel or PET pixel, for PET-CT it refers to, the reference document is a PhD thesis</td>
<td>Suspension of type C and D is unjustified. There is enough scientific disagreement in the hybrid imaging field to prevent mandating the results of just one study/paper as a suspension-level rule.</td>
<td>Accepted. In table 3.10 on page 67 replace suspension level by “More than ±1 PET pixel size”, remove the reference from the table and the list of references.</td>
</tr>
</tbody>
</table>
The Nuclear Medicine Section

The suspension levels stated are intended to assist in the decision making process regarding the need for recalibration, maintenance or removal from use of the equipment considered. Each part of this section is comprised of a brief introduction and a list of relevant equipment.

For each piece of equipment, a brief introduction, a table with the critical performance parameters and the suspension levels are given.

References to recommended test methods for each parameter are also given.
Contents of Nuclear Medicine Section

- Introduction
- Nuclear Medicine Therapeutic Procedures
- Radiopharmacy Quality Assurance Programme
- In-Vitro Diagnostic Equipment
- Gamma Camera based Diagnostic Procedures
- Positron Emission based Diagnostic Procedures
- Hybrid Diagnostic Systems
- Intra-Operative Probes
Introduction to Suspension Levels: Nuclear Medicine

- **Introduction**
  
  This is a general introduction highlighting the peculiarities of Nuclear Medicine equipment.
  
  It also states which equipment will be considered and why.

- **Therapeutic Procedures**
  
  - Activity measurement instruments
  
  - Contamination monitors
  
  - Patient dose rate measuring instruments
Therapeutic Procedures

Activity measurement instruments

<table>
<thead>
<tr>
<th>Physical Parameter</th>
<th>Suspension Level</th>
<th>Reference</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background response</td>
<td>&gt; 1.5 X Usual Background</td>
<td>IEC (2006) (section 4.1)</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IEC (1994c) (section 8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPL, 2006</td>
<td></td>
</tr>
<tr>
<td>Constancy of instrument</td>
<td>± 7%</td>
<td>IEC (2006) (section 4.2)</td>
<td>C</td>
</tr>
<tr>
<td>response</td>
<td></td>
<td>NPL, 2006</td>
<td></td>
</tr>
<tr>
<td>Instrument Accuracy</td>
<td>± 5%</td>
<td>IEC (1994c) (section 3)</td>
<td>B</td>
</tr>
<tr>
<td>Instrument Linearity</td>
<td>± 5%</td>
<td>IEC (2006) (section 4.3)</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IEC (1994c) (section 4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPL, 2006</td>
<td></td>
</tr>
<tr>
<td>System reproducibility</td>
<td>± 5%</td>
<td>IEC (1994c) (section 5)</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPL, 2006</td>
<td></td>
</tr>
<tr>
<td>Sample volume characteristics</td>
<td>± 10%</td>
<td>IEC (1994c) (section 7)</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPL, 2006</td>
<td></td>
</tr>
<tr>
<td>Long-term reproducibility</td>
<td>± 7%</td>
<td>IEC (1994c) (section 9)</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPL, 2006</td>
<td></td>
</tr>
</tbody>
</table>
Radiopharmacy Quality Assurance Programme

- Radiopharmacy for gamma camera based diagnostic procedures
  - Activity Measurement Instruments
  - Gamma Counters
  - Thin Layer Chromatography Scanners
  - Contamination Monitors

- Radiopharmacy for positron emission based diagnostic procedures
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- **Gamma Camera based Diagnostic Procedures**
  - Introduction
  - Planar Gamma Camera
  - Whole Body Imaging System
  - SPECT System
  - Gamma Cameras used for Coincidence Imaging
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- Gamma Camera based Diagnostic Procedures
  - Planar Gamma Camera

<table>
<thead>
<tr>
<th>Physical Parameter</th>
<th>Suspension Level</th>
<th>Reference</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrinsic Spatial Resolution</td>
<td>More than 1.10 expected value</td>
<td>IEC (2005a), Section 4.3</td>
<td>A</td>
</tr>
<tr>
<td>Intrinsic Spatial Non-Linearity</td>
<td>More than 1.10 expected value</td>
<td>IEC (2005a), Section 4.4</td>
<td>A</td>
</tr>
<tr>
<td>Differential and Integral Intrinsic Non-uniformity</td>
<td>More than 1.10 expected value</td>
<td>IEC (2005a), Section 4.5</td>
<td>A</td>
</tr>
<tr>
<td>Intrinsic energy resolution</td>
<td>More than 1.10 expected value</td>
<td>IEC (2005a), Section 4.6</td>
<td>A</td>
</tr>
<tr>
<td>Multiple window spatial registration</td>
<td>More than 1.10 expected value</td>
<td>IEC (2005a), Section 4.7</td>
<td>A</td>
</tr>
<tr>
<td>Intrinsic count rate performance in air</td>
<td>Less than 0.9 expected value</td>
<td>NEMA (2007a), Section 2.8</td>
<td>A</td>
</tr>
<tr>
<td>System Spatial Resolution with scatter</td>
<td>More than 1.10 expected value</td>
<td>IEC (2005a), Section 4.3</td>
<td>A</td>
</tr>
<tr>
<td>Differential and Integral System Non-uniformity</td>
<td>More than 1.10 expected value</td>
<td>IEC (2005a), Section 4.5</td>
<td>A</td>
</tr>
<tr>
<td>Artefacts</td>
<td>Any artefact that can impact on diagnosis</td>
<td></td>
<td>C</td>
</tr>
</tbody>
</table>

* Expected values are the values for each parameter measured or agreed during the acceptance testing.
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- Positron Emission based Diagnostic Procedures
  - Introduction
  - Positron Emission Tomography (PET) System

<table>
<thead>
<tr>
<th>Physical Parameter</th>
<th>Suspension Level</th>
<th>Reference</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spatial Resolution</td>
<td>FWHM_{observed} &gt; 1.10</td>
<td>IAEA (2009) (section 5.1.1)</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>FWHM_{expected}*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>S_{TOTobs} &lt; 0.90 S_{TOTexp}</td>
<td>IAEA (2009) (section 5.1.2)</td>
<td>A</td>
</tr>
<tr>
<td>Scatter fraction, count losses and random measurements</td>
<td>NEC_{obs} &lt; NEC_{rec}</td>
<td>IAEA (2009) (section 5.1.3)</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>SF_{obs} &gt; 1.10 SF_{exp}*</td>
<td></td>
<td>A</td>
</tr>
<tr>
<td>Energy resolution</td>
<td>RE_{obs} &gt; 1.10 RE_{exp}*</td>
<td>IAEA (2009) (section 5.1.4)</td>
<td>A</td>
</tr>
<tr>
<td>Image quality and accuracy of attenuation and scatter correction</td>
<td>Unacceptable visual assessment</td>
<td>IAEA (2009) (section 5.1.5)</td>
<td>A</td>
</tr>
<tr>
<td>Coincidence timing resolution (TOF)</td>
<td>RT_{obs} &gt; 1.10 RT_{exp}*</td>
<td>IAEA (2009) (section 5.1.6)</td>
<td>A</td>
</tr>
<tr>
<td>Uniformity</td>
<td>%NU_{obs} &gt; 1.10 %NU_{exp}*</td>
<td>IAEA (2009) (section 6.1.4)</td>
<td>A</td>
</tr>
</tbody>
</table>

* Expected values are the values for each parameter measured or agreed during the acceptance testing.

FWHM = Full Width at Half Maximum
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- Hybrid Nuclear Medicine Equipment
- Intra-Operative Probes

Table 3.11 Suspension Levels for a SLN intra-operative gamma probe system

<table>
<thead>
<tr>
<th>Physical Parameter</th>
<th>Suspension Level</th>
<th>Reference</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spatial Resolution</td>
<td>FWHM &gt;15mm for lymph nodes in head, neck and supraclavicular region FWHM &gt; 20mm for lymph nodes in extremities, axilla and groin</td>
<td>Wengenmair and Kopp (2005) NEMA (2004) (section 3.5)</td>
<td>C</td>
</tr>
<tr>
<td>Shielding</td>
<td>&gt; 0,1 of minimum system sensitivity</td>
<td>Wengenmair and Kopp (2005)</td>
<td>C</td>
</tr>
</tbody>
</table>
Conclusions

1. The Reviewing Team is of the opinion that the current version of the Nuclear Medicine section is as good as can be, taking into account the available bibliography on the subject and the technology currently in clinical use.

2. The Reviewing Team will consider the recommendation of the Workshop on Wednesday the 7th of September in order to finalise the section. So please make sure that your concerns are included in the Workshop’s conclusions and recommendations.