SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM

SPECIALIST TECHNICAL COMMITTEE MEETING:
QA Diagnostic X-Ray Equipment

Minutes of the Meeting held at the NLA Building, Corner of Gen. van Ryneveld Street and De Havilland Crescent, Persequor Park, Lynnwood, Pretoria on Thursday, 27 September 2012 at 09:00

Present:  
Mr E Smit      Chairman - Department of Health (DoH)  
Mrs L Grundlingh SANAS - Field Manager: Inspection  
Mr P Wolff      AXIM  
Mr CA Hodgson   Wright-Millners  
Mr J Smith      Wright-Millners  
Mrs Z Msimang   NMiSA  
Mr E Smit      SANAS – Scribe

Apologies:  
Mr D Wash      MEDICLINIC for HASA  
Mrs N Tsoeu    Gauteng Health - Central Office  
Mr A Nortje    Drakemed  
Mr S Bellmann   Siemens  
Mr J Fernandos Phillips  
Mr J Morgan    Phillips  
Mr S Jozela    NMiSA  
Dr W Rae       Assessor - UFS  
Mrs A Sweetlove Assessor - Private  
Mr H de Vos    Assessor - Netcare  
Mr NJ v/d Merwe Assessor - NECSA  
Mr L Chesango  SANAS – Lead Assessor: Inspection

NO.      ACTION BY     DATE
1. OPENING AND WELCOME     
The chairman opened the meeting and welcomed those present All  
and asked members to introduce themselves.  
A special welcome to the new Field Manager: Inspection – Linda Grundlingh
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<th>NO.</th>
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<tr>
<td>2.</td>
<td>APOLOGIES</td>
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<td>Apologies noted on the attendance register for the members who could not attend.</td>
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<td>3.</td>
<td>SIGNING OF ATTENDANCE REGISTER</td>
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<td>All members present signed the attendance register and the confidentiality clause was acknowledged</td>
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<td>4.</td>
<td>FINALISATION OF AGENDA</td>
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<td>Agenda finalized with no new items added to the agenda.</td>
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<td>5.</td>
<td>APPROVAL OF MINUTES FROM THE PREVIOUS MEETING</td>
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<td>Previous minutes were accepted with no alterations as a true reflection of the meeting held.</td>
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<td>6.</td>
<td>MATTERS ARISING FROM PREVIOUS MEETING</td>
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<td>6.1</td>
<td>(6.1) Calibration and Traceability</td>
<td>All</td>
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<td>NMISA gave feedback on their calibration capabilities for the QA X-Ray Industry. NMISA is currently capable of providing calibration, traceable to national standards, for light-meters and radiation dosimetry.</td>
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<td></td>
<td>NMISA is currently not capable of providing kV calibration. The possibility to perform kV calibration will be investigated. Peter Wolff has indicated that Axim has an invasive kV meter that could be used.</td>
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<td>NMISA is also planning to provide dosimetry and dose rate calibration by 2014. NMISA has also indicated that hvl calibration will also be possible.</td>
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<td>6.2</td>
<td>(6.3) Compliance with Licence Conditions</td>
<td>All</td>
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<td>DoH reported that test and inspection results are still not being reported in a timeous manner as required by accredited inspection bodies’ licence conditions.</td>
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<td>Inspection Bodies are reminded to submit their results in electronic format to the DoH at least 4-weeks after the Inspection was done.</td>
<td>All</td>
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<td>All</td>
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<td></td>
<td>SANAS</td>
<td>07 March 2013</td>
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<td>SANAS Assessors</td>
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Information submitted is linked to a facility's licence agreement for quality assurance purposes.

After some discussion, the Committee decided that the reporting requirements shall be incorporated in the SANAS TR 78 document.

The reporting period (4-weeks) will be discussed at the DoH QA X-Ray Forum of 28 September 2012 as well.

### 6.3 (6.5) Dental Inspection Bodies

Background to the accreditation process for the Dental QA X-Ray process was given by DoH as well as feedback from the Dental QA X-Ray Stakeholders meeting that took place on 06 May 2011 in Gauteng.

DoH is in the process of preparing for Accreditation, the planned implementation date is 2013. Implementation date of Acceptance tests: January 2013. Implementation date of Routine tests: January 2014.

SANAS reported that to date no Dental QA X-Ray organisations have applied for Accreditation, despite the fact that approximately 9 enquiries had been received.

The DoL indicated that if no application for Accreditation is processed by 02 January 2013, the deadline will be extended. Once an application is in the Pre-assessment phase (see P 15 for detail on SANAS website [www.sanas.co.za](http://www.sanas.co.za)) the DoH intends to enforce the Dental Inspection Body Licence to Perform Maintenance Tests on Dental Diagnostic X-Ray Imaging Systems.

### 6.6 (6.7) Progress on ISO/IEC 17020: 2012

ISO/IEC 17020: 2012 – *Conformity assessment - General criteria for the operation of various types of bodies performing inspection* was published by ISO on 01 March 2012 and ILAC gave a 3-year transition period from date of publication.

This means that all accredited Inspection Bodies must complete the transition by 01 March 2015.

SANAS published their 17020 Transition Plan (Rev 02) with a target date of 01 March 2015 for finalisation of the process. Please see the SANAS website [www.sanas.co.za](http://www.sanas.co.za) “Announcements”-page for detail.

All inspection documents (R & TR), forms and checklists have been updated to reflect ISO/IEC 17020: 2012 and Inspection Bodies should familiarise themselves with the updated
6.5 **South African Health Products Regulatory Authority (SAHPRA)**

Government is in the process of establishing South African Health Products Regulatory Authority (SAHPRA) as the body that will be responsible for the control (regulation) of all medical devices.

It is envisaged that SAHPRA will be functional in the future, however at this moment it is not possible to say when.

DoH report back on SAHPRA developments:

At this stage it looks like Radiation Control will move to SAHPRA and will continue with their function as prescribed in the Hazardous Substance Act, Act 15 of 1973 as Amended, in the short to medium term.

7. **NEW ITEMS**

7.1 **DoH Stakeholders meeting – 28 September 2012**

DoH Stakeholders meeting will be at Siemens South Africa, 300 Janadal Avenue, Halfway House, Midrand Friday, 28 September 2012 at 12H00.

Feedback will be given at the next STC meeting.

8. **GENERAL**

8.1 **(1) STC Membership**

All members are reminded of the terms of reference as members of the STC QA X-Ray, please see P 19-03 - *Terms of Reference, Registration and Responsibilities of Specialist Technical Committees* on the SANAS website: [www.sanas.co.za](http://www.sanas.co.za)

All members were reminded to submit an update CV, completed F 20 to SANAS at least every 2 to 3-years.

8.2 **Accreditation Stats**

See SANAS website [www.sanas.co.za](http://www.sanas.co.za) for Accredited Organisations.

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<tr>
<th>Enquiries</th>
<th>Applications</th>
<th>Accredited</th>
<th>Suspended</th>
<th>Withdrew</th>
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<tr>
<td>09 (Dental)</td>
<td>0</td>
<td>14</td>
<td>0</td>
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9. **CLOSURE**
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<td>All</td>
<td>07 March 2013</td>
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Date of next meeting:

- **07 March 2013**
- 27 September 2013

DoH QA X-Ray Stakeholders meeting – 2013. TBC

The meeting adjourned at 12:00