

Audit Report: 21 CFR Part 11

***StabNet 1.0* for control of stability measurement devices**



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Audit Date:	07.03.2012 ¹
Auditor:	Sieghard Wagner, mech. engineer (grad.), Chemengineering Business Design GmbH
Audit Purpose:	Proof that the <i>StabNet 1.0</i> software, used for the control of stability measurement devices, is in compliance with of 21 CFR Part 11.
Description:	<p><i>StabNet</i> is a PC software for the control of stability measurement devices. It features creating methods, performing single and multiple analyses, evaluating data (results, statistics, limit monitoring) and generating reports.</p> <p>The software was developed by Metrohm Ltd. in accordance with ISO 9001 requirements regarding design, manufacturing and maintenance.</p>
Investigation:	<p>The functions and properties of the system mentioned above are audited in regards to the requirements of 21 CFR Part 11 and the current interpretations.</p> <p>During the audit the following items were examined:</p> <p>Validation, documentation, audit trail, electronic copies, access rights, user access, password, access violations, sequence of steps, plausibility, device check, data encryption, electronic signature.</p>
Operator Responsibility:	<p>Compliance with the requirements of 21 CFR Part 11 can only be met in connection with the operational environment. The requirements for such an environment encompass:</p> <ul style="list-style-type: none">• Technical environment, data management• Training• Administration• Standard Operating Procedures (SOP).
Summary:	<p>The software is compliant with the following 21 CFR Part 11 requirements:</p> <ul style="list-style-type: none">• 11.10 (b), (d), (e), (f), (g), (h)• 11.50, 11.70• 11.300 (a). <p>The software is compliant with the following 21 CFR Part 11 requirements with support of the operator:</p> <ul style="list-style-type: none">• 11.10 (a), (c), (i), (j), (k)• 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d). <p>The software supports electronic signatures.</p>


Sieghard Wagner

¹ At the date of the audit some quality documents have not been finalized – these open issues were checked in a separate review at the end of April 2012.