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Wenclawiak, B., Koch, M. and Hadjicostas, E., Quality Assurance in Analytical Chemistry, ISBN 3-54040-57-8, Springer-Verlag, Berlin, Germany, 2004.

Funk, W., Dammann, V. and Donnevert, G., Quality Assurance in the Analytical Laboratory, ISBN 3-527-31114-9, Wiley-VCH, Weinheim, Germany, 2006.

Hibbert, D. B. and Golding, J. J., Quality Assurance in the Analytical Chemistry Laboratory, ISBN 0-195-1621-29, Oxford University Press, Oxford, UK, 2006.

Lineby N. and Parel, L. Geolerati Palaciphenof Golad Subphing Stratcher alBBR 0-55494-41214 (Jan 1971) Satisfy of Chemistry, Cambridge, UK, 1995

Destau 201-9: The Royel Socialy of Chindrey? Chariking? URO199700 Juorin Interney Dul Press, L. Wilds and Ocalification in Analysical Lafterneysian (SBN, 1:5788):1980. Spinkarshired Press, Bultula Grove, H., USA, 1998. "Automatication from a science of the second statement of the second sta

(Analytical Chemistry Series), ISBN 0-84932-3762, Interphane Press/CRC Press, Boca Raton, PL, USA, 2006.

Daugers, C., Patid Analytical Methods and Procedures. ISBN 0-85404-482-5, The Royal Society of Chemistry, Combinitge, UK, 2000.

and Editors, ISBN 0-935584-70-6, Association of Official Analytical Chemists (AOAC) Informational, Gaithersburg, MD, USA, 2000.

and Editions. USEN 0-948926-15-5. (Eurochem), Co-operation on International Tracesbility in Analytical Chernistry (CITAC), 2000. [http://www.surachem.org] (accessed 11 December, 2005).

Boca Euron, FL. USA, 2000.

Chemisury, Cambridge, UK, 2001.

Teddingroot, UK, 2003.

Society of Chemistry, Cambridge, UK, 2003.

ment Performance Verification, ISBN 0-471-25953-5, John Wiley & Sons, Inc., Hoboken, NJ, USA, 2004.

185 5. Chapman & Hall/CRC Press, Boca Raton, FL, USA, 2004

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