Quality

Quality assurance and control forms an integrated part of the analyses performed and of the work of ALS Scandinavia as a whole. Quality assurance (QA) is the generic term for all activities required to maintain quality in the analytical results. The QA activities affect many fields such as organization, training, equipment, methods, etc.

The QA is organized and documented within the laboratory´s QA system. The QA system is a prerequisite for laboratory accreditation. The accreditation is a third-party acknowledgement of competence and is comparable to ISO 9000 certification in industry. For a laboratory to be accredited, compliance with international QA standards must be confirmed both by an initial assessment and by recurrent audits. In Sweden, accreditation and control of accredited laboratories is the responsibility of SWEDAC. SWEDAC cooperates internationally with other accreditation bodies, which implies that its accreditation is accepted in several other countries.

Accreditation by SWEDAC pertains to specific analytical methods. Non-accredited analyses are also subject to QA and many parts of the QA system are common to all analyses. However, accredited analyses must meet special requirements e g regarding documentation.

ALS Scandinavia's accreditation certificates and lists of accredited methods are published on our website: www.alsglobal.se/en/als-scandinavia/quality.

Accreditation by SWEDAC is accepted in:

Australia	Finland	Israel	Norway	Switzerland
Austria	France	Italy	Poland	Taiwan
Belgium	Germany	Japan	Portugal	Turkey
Brazil	Greece	Republic of Korea	Romania	UK
Bulgaria	Hong Kong	Latvia	Singapore	USA
Canada	Hungary	Lithuania	Slovakia	Vietnam
PR of China	Iceland	Luxembourg	Slovenia	
Czech Republic	India	Malta	South Africa	
Denmark	Indonesia	Netherlands	Spain	
Estonia	Ireland	New Zealand	Sweden	

Quality control

Quality Control (QC) is the specific control of an analysis to verify the results before reporting. There is also more general control of the laboratory's analytical methods and their use. QC is an important component of the QA system.

The most important tools for controlling chemical analyses are interlaboratory comparisons and certified reference materials.

In Interlaboratory Comparisons, several laboratories analyze subsamples of one and the same homogeneous sample. If a sufficient number of laboratories participate and the analytical methods are reliable, the resulting mean or median may serve as a reference value. ALS Scandinavia participates regularly in interlaboratory comparisons for trace metals in water, blood, urine etc.

Certified Reference Materials (CRM) are authentic materials (e g seawater, plant material, steel etc) in which concentrations of various substances have been accurately determined by means of several analytical techniques and laboratories, usually in international cooperation. Many CRM:s are commercially available. The material is followed by a certificate with known (certified) values to which a laboratory can compare its results and thus check the accuracy in its own analysis. ALS Scandinavia routinely uses CRM:s in the analyses.

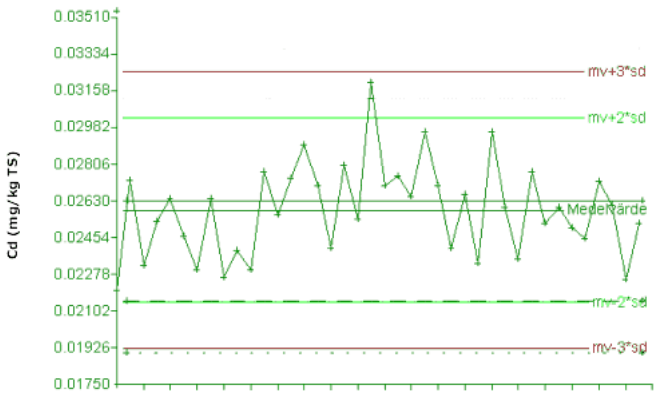
Examples of certified reference materials used by ALS Scandinavia

Sample type	Name	Certified for	Issued by
Sludge	BCR 144R	Trace elements (total concentrations and aqua regia leachable fractions	CBR
Sediment	GBW 07310	Main elements, trace elements, LOI	IGGE
Soil	CRM027-050	Main elements, trace elements	RTC
Coal fly ash	NIST 1633b	Main elements, trace elements	NIST
Fish muscle	DORM-2	Trace elements, methyl mercury	NRC

CBR (=BCR) Community Bureau of Reference
CCRMP Canadian Certified Reference Material Project
IGGE Institute of Geophysical and Geochemical Prospection (China)
NIST (former NBS) National Institute of Standards and Technology, USA

Control charts

For all accredited analyses there are control charts showing long-term results for a reference sample. This sample is often a CRM. In each analysis, the reference sample is analyzed together with the ordinary unknown samples. The results statistics is used to calculate "action limits" representing certain concentration levels above and below the mean. If at any time the result for the reference sample falls outside these limits, the analysis is not approved. This prevents accidental errors from causing errors in reported results. The control charts are also evaluated yearly with respect to agreement with reference/certified values, precision (i e the agreement between analyses on different days), limits of detection and quantitation, and trends (changes over time). This evaluation reveals weaknesses and forms a basis for measures to continuously improve the analyses.



Control chart, showing analyses of CRM NIST 1547 (peach leaves) by ICP-SFMS from 1999-11-13 to 2000-06-13. The certified cadmium concentration is 0.026±0.003 mg/kg DW.

Validation of analytical methods

Validating an analytical method means to experimentally test and to document that the method fulfils the requirements for its intended use. Within the drug industry, where analyses are usually strongly specialized for defined sample types, ALS Scandinavia often performs validation on a contract basis together with method development. Validation is normally carried out according to procedures that are internationally accepted (ICH Q2A, B), and which include the following analytical performance criteria:

- Accuracy
- Precision
- Specificity
- Detection limit
- Quantification limit
- Linearity
- Range
- Robustness

A validation project does not always include all the above items. It is based on a validation protocol, which is defined by the laboratory or by the customer, and on which both parties agree. The validation protocol may specify the requirements for the method, e g regarding detection limits. The final results are documented in a validation report.

Uncertainty in measurement

Even with the best QA and QC, each result of a chemical analysis inevitably has an uncertainty associated with it. For the customer it is important to know that this uncertainty exists and sometimes also to have information on its magnitude. However, calculations of uncertainty in chemical analyses are complicated and only relatively recently have international guidelines for calculating and reporting uncertainty been issued and accepted. SWEDAC now requires the implementation of such guidelines in Swedish accredited laboratories.

The uncertainty can be expressed as an interval around the reported value within which the "true" value lies with high (e g 95%) probability, e g 5.2 ± 0.4 µg/l. The calculation requires that all significant sources of uncertainty be included (such as instrument instability, uncertainty in balances and volumetric equipment, errors in calibration standards etc). The guidelines specify how these contributions shall be taken into account and how the uncertainty shall be calculated and reported together with the analytical value. ALS Scandinavia has constructed and implemented a model for calculation of uncertainty that is based on the international guidelines and adapted to its own analyses and QC routines. A characteristic is that uncertainty is calculated for each sample individually and is directly linked to the measurement on this sample. To enable estimations in advance, tables with approximate uncertainty values are used. The "expanded" uncertainty, calculated according to the new regulations, often seems large. It should then be borne in mind that the "expanded" uncertainty is not to be compared with the CV values (relative standard deviation in %), previously reported by laboratories as a measure of uncertainty. The new calculation model directly doubles these values, and other sources of uncertainty, not included in a CV value, is also taken into account.

Control of subcontractors

For part of the analyses, ALS Scandinavia uses subcontractors in Sweden or abroad. These are usually accredited for the methods used by an internationally approved accreditation body, which is normally considered sufficient to assure analytical quality.

However, for some analyses, different accredited methods may yield non-comparable results. This holds especially for some organic compounds (e g PAH) that are extracted from solids (e g soil) by various solvents. The extraction is normally not 100% effective, i e the total content is not extracted. Different extraction methods may differ in efficiency and thus yield different results.

Analytical reports from ALS Scandinavia contain information on subcontractors used, as well as on methods used in sample preparation and analysis. Accredited analyses performed by a subcontractor are reported without the accreditation mark, if the report is issued by a non-accredited laboratory (valid fro reports for Oslo). If required, the accreditation marked original report from the subcontractor can be obtained from ALS Scandinavia.

The most important subcontractors are controlled by ALS Scandinavia by means of recurrent audits on-site.

About limits of detection and quantification

An analytical method's limit of detection (LOD) is the lowest concentration at which a certain substance can be detected, i.e., where it can be assured that a certain substance is present. Regarding the actual concentration, a result close to the LOD is very uncertain, i.e., the analysis can not be regarded as quantitative. The LOD is normally defined as three times the standard deviation achieved from analysis of blank samples (3s).

The limit of quantification (LOQ) is the minimum concentration that can be quantitatively determined with satisfying certainty. The LOQ is normally defined as 10 times the standard deviation (10s) for blank samples, and is thus approximately three times higher than the LOD.

ALS Scandinavia uses limit of report as a common term for the minimum reported concentration (below this concentration, < is reported), regardless of how it has been calculated. The limit of report for ALS Scandinavia's analyses is usually determined as the LOQ. The reason for this is that all reported concentrations should be possible to regard as quantitative without too much uncertainty. This is in accord with the approach of the accreditation body (SWEDAC).

Chain of custody

Chain of Custody (COC) is a procedure which provides a written record that can be used to trace the possession of a sample from the moment of its collection through its introduction into a data set. The purpose is to guarantee the integrity of the sample, i e that it has been properly handled and that there is no possibility for mixup, tampering, or extraneous contamination. COC may be required in cases where analytical results become subject to litigation, e g in connection with real estate purchase.

COC can be ordered for samples that are delivered or sent to ALS Scandinavia in Täby. COC is subject to a charge and shall be ordered when sample containers are ordered from Analytica. Further instructions are then sent together with the sample containers, that are delivered in sealed boxes (on request, the containers can also be individually sealed). A special COC form is enclosed, which shall be used as the order form for COC samples. When the analysis is finished, ALS Scandinavia will return the COC form together with the analytical report. The completed COC form is a proof that the samples have been handled with COC up to the moment when ALS Scandinavia (i e ALS Scandinavia's assigned "custodian") has taken on responsibility for their integrity.