

# ROMIL Distillations



***Taking a Closer Look at ROMIL***



PrimAg® Bulletin

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**Traceable. Accredited. Inspired.**



Way back in 2002, ROMIL became the first worldwide commercial manufacturer of elemental certified reference materials (CRMs) to be accredited to ISO 17025 as a Calibration Laboratory. Since then Romil have continued to build on the PrimAg® range and have recently gained accreditation for a number of new products.

During recent years the appearance of ISO Guide 34 accredited CRMs on the market has altered the selection

process of reference materials. Many analysts are now unsure of exactly what is required of them in order to comply with their UKAS accreditation status. To clarify some of the issues involved in CRM selection Romil has put together a range of Frequently Asked Questions.(P.T.O)



Very briefly, ISO Guide 34 covers all the elements of ISO 17025 and some additional ones for production, storage and distribution (usually addressed by ISO 9001). Effectively, Romil have long been doing all that Guide 34 requires. So to continue to provide the most extensive service to their customers they will be transferring their accreditation from ISO 17025 to ISO Guide 34 during 2010.

Please note that ISO 17025 accredited CRM's are still valid and can still be used in an accredited testing laboratory. It would be perverse to suggest otherwise. However, Romil hope that by offering ISO Guide 34 accredited CRMs, they will address the hassles that have been caused by misunderstandings on the part of both laboratories and assessors.

We hope you have found this bulletin interesting and of course, we welcome any comments or questions you may have. PrimAg is a registered trademark of ROMIL Ltd.



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## ROMIL PrimAg® Frequently Asked Questions (FAQ)

### What is ISO Guide 34?

ISO Guide 34:2000 – General requirements for competence of reference material producers

This guide was created to ensure that reference material producers (RMPs), are competent to manufacture their products to a certain quality fit for purpose. It covers all the elements of the established international standard ISO 17025 and some additional ones for production, storage and distribution. This is particularly important with complex materials such as soil, sludge and seawater where the traceability, homogeneity and stability are not necessarily inherent characteristics of the product. However, for simple, stable elemental reference materials such as ROMIL PrimAg, where there is a much simpler line of traceability to SI units - particularly the unit for 'amount of substance', the mole - these extra points are not as relevant.

### UKAS have said we must use CRMs that are accredited to ISO Guide 34 - why is this?

UKAS-accredited testing laboratories should be using either ISO Guide 34 or ISO 17025 accredited certified reference materials wherever possible. If they are using ISO 17025 accredited CRM's then they may have to question the stability, homogeneity, transportation and storage. Since these points can be clarified by referring to the certificate of calibration, the user's own experience or the inherent properties of these types of products, no further validation should be required. Furthermore, since ROMIL PrimAg CRMs have been accredited by UKAS to ISO 17025 since 2002 (and still have valid accreditation), it would be perverse to suggest that they cannot be used in a UKAS-accredited testing laboratory, or indeed any other laboratory that is accredited by an organisation that is a signatory to the ISO 17025 multi-lateral agreement.

### Why does ROMIL not have ISO Guide 34 and is ROMIL seeking to achieve ISO Guide 34 accreditation for PrimAg reference materials?

When Romil introduced their range of PrimAg CRM's (in 2002) the only accreditation option available to them was ISO 17025 as a calibration laboratory. Romil were the first organisation worldwide to achieve such accreditation and remained so for a number of years.

However, accreditation authorities felt that something else was required for reference material producers and started accrediting such organisations to ISO Guide 34. This despite the fact that Guide 34 is not an international standard and that there are no multi-lateral agreements (MLA) in place for it. Nevertheless, Guide 34 has now become the 'fashion item' for the reference material community and as a result steps are being brought forward to establish it as a proper international standard in its own right - ISO 17034.

Therefore, in order to continue to provide their customers with a top range of reference materials, both in their performance and for ease of administration within current reference material practices, Romil have decided to transfer their accreditation from ISO 17025 calibration to ISO Guide 34. Romil expect this to be in place during 2010.

### Will more products be available under ISO Guide 34 than ISO 17025?

Once ISO Guide 34 has been awarded to a RMP for the competency to manufacture CRM's, they have the authority to self-certify these products. Therefore, more products can be offered under this scheme so long as they are manufactured in accordance with the Guide. In addition newly accredited products require less administration by the accrediting body so can be brought to market in a shorter time-scale.

### Will we have to pay more for ISO Guide 34 accredited PrimAg reference materials?

From the beginning, their policy has been to provide high quality accredited reference materials, but at the price level of their non-accredited counterparts. Be assured that this will continue.

### Do all RMP's accredited with ISO Guide 34 have to work within the same uncertainty estimations as each other and if so are the tolerances stipulated within ISO Guide 34?

No, they do not and this is not a part of ISO Guide 34. There is no multi-lateral agreement (MLA) in place for ISO Guide 34 yet which means that different accreditation bodies are allowing different schedules of accreditation. Some of these schedules contain very little information on best measurement capability. In ISO 17025 the schedules follow a more standardised format so the user can make comparison of different products before buying. In addition CRM's have to be approved before coming to market. Under ISO Guide 34, RMP's can self-certify so it is possible that sub-standard products could be released on to the market. The uncertainty calculation is stated on the certificate but by the time you have read the certificate you have probably bought the product.

### UKAS have asked that if we use ISO 17025 accredited CRM's then we should question the stability, homogeneity, transportation and storage. How do we do this?

This is only if the product is not inherently stable and homogenous. In the case of PrimAg CRMs, being simple pure solutions and compounds, the characteristics are stable and homogeneous. The uncertainty estimation is outlined on the certificate of calibration provided with all PrimAg-plus and PrimAg-extra products. PrimAg products are all packed appropriately for any type of transportation, be it road, sea or air. They are packaged in high density polyethylene bottles, which are basically inert. A recommendation of the storage conditions and expiry date is displayed on the product label and normally says 'store in a cool dry place'.

Also, bear in mind that UKAS state 'where they (the testing laboratory) are buying a range of similar materials (e.g metals standards) from a RMP it may be acceptable to review the details for one or two materials before accepting the range'.

The transportation and storage aspects have in any case long been addressed by our registration to the ISO 9001 quality system standard. And, indeed, ISO 17025 itself requires that operations are conducted in a suitable laboratory environment. All Guide 34 does, in effect bring these two standards together in one.