

**INTI-QUÍMICA**  
**INTERNAL AND CROSSED AUDITS**

**2012 Crossed Management Audit**

Lead Auditor: Gladys Mastromónaco (INTI-SAI)

Date: 09-28-2012

This audit revealed 5 non-conformities, all resolved to date.

<p><b>1.-</b> Copy N° 1 is not included in <i>Document Distribution List F-01.2 Ed 2</i>, implemented by the trace laboratory. The laboratory stated that the number 2 entered in the column of number of copies corresponds to the number of circulating copies instead of the pertinent identification assigned to them, such as copy number 1 and 2.</p> <p><b>Corrective action:</b> the corresponding record was revised to include the correct number for each copy, instead of the total number of copies.</p>
<p><b>2.-</b> The <i>Software Record F-01.4 Ed 2</i> form is not included in the Trace laboratory, for example, for the atomic absorption equipment, nor is the <i>Consumables Stock Record F-04.4 Ed 2</i> form for reagents present at the Drug and Water Laboratories.</p> <p><b>Corrective action:</b> the corresponding software record shall be implemented in the trace laboratory, as well as the consumables record in the Water and Drugs laboratories.</p>
<p><b>3.-</b> The method applied by the trace laboratory to maintain the integrity of items to be tested, since their entry into the lab up to their final disposal, as stated in <i>PG-03 Ed 2, item 6.2</i> is not clearly documented. It reads “<i>these procedures are specific to each centre area according to the characteristics of the samples received.</i>”</p> <p><b>Corrective action:</b> Procedure PG-03 shall include the method to be applied in order to keep integrity of test items in the laboratories.</p>
<p><b>4.-</b> The provider company Eurolab is not rated according to <i>Provider Evaluation F-04.2 Ed 2</i> form.</p> <p><b>Corrective action:</b> Eurolab shall be rated. Also, PG-04 “Service and Supply Procurement” procedure shall be revised so as to improve the provider evaluation process.</p>
<p><b>5.-</b> Staff training is not accounted for in the Management Review.</p> <p><b>Corrective action:</b> Information regarding training received by the Chemistry area staff during the period under review shall be included in the Final Management Review Report.</p>

**Internal Technical audits (2011-2012)**

The following procedures were audited (September 2011)

Note: Considering that, during 2012, a peer review was held to all the methods, no internal audits were performed in that year.

- Determination of Cr in acid solutions (PAAMet-02).* Auditor: Pablo Álvarez  
Non-conformities: 1 – solved
- Determination de nitrites in calibration solutions.* Auditor: Mabel Puelles  
Non-conformities: 3 – solved

<p>1.- The format of the procedure PAAMet-02 does not follow the guidelines established in PG-01</p> <p><b>Corrective Action:</b> The procedure was modified in order to adapt it to PG-01.</p>
<p>2.- In par. 6.2.1, it is declared as mother solution 1000 mg/L of NO<sub>2</sub> It must be 1000 mg/L of NaNO<sub>2</sub> .</p> <p><b>Corrective Action:</b> It was a mistake, which was corrected, in the new version of the procedure</p>
<p>3.- The sodium nitrite solution used as QC is the same as for the calibration curve. It must be a MRC</p> <p><b>Corrective Action:</b> a new MRC was purchased, exclusively for QC purposes</p>
<p>4.- A non-qualified analyst carries out the procedure during the audit</p> <p><b>Corrective Action:</b> He was qualified, but the corresponding record was Missing. It was solved</p>