

## Re-Certification of Lapsed PTM:

- 1.0 Lapsed PTM may be submitted for re-certification if no changes have been made to the test kit.
- 2.0 Re-certification fee is US \$5,000.
- 3.0 The sponsor company must collect data (at the new production location if there is a new production location) that compares the performance of the lapsed test kit to the appropriate reference method(s).
- 3.1 Comparison data for each reference method must be submitted if more than one reference method was examined in the original validation study.
- 3.2 Copies of the original validation study are available from the AOACRI for a fee of US \$100.00.
- 3.3 The sponsor company may elect to develop its own study design, or use the AOACRI Consulting Service (see <http://www.aoac.org> Research Institute for Consulting Service details).
- 4.0 The sponsor company must and submit a formal report containing the results of the comparison study.
- 5.0 The new data collected for re-certification must demonstrate that the kit performs as well or better than the original data.
- 6.0 If approved for re-certification the kit will be certified until the end of the calendar year. Renewal fees for the 1st year following re-certification will be pro-rated based on the month the kit is re-certified.
- 6.1 Thereafter, annual renewal fees will be assessed in full every year as long as the company desires to retain PTM status for the test kit (and assuming the company and kit complies with all AOACRI policies and procedures).