



December 2007

## Reasons contracting of test centre should remain with Registration Authority

N.B. References below to “ICAR” should be taken to read:

“Service-ICAR, Via G. Tomassetti 3, 1/a, 00161 Rome, Italy”.

ISO, as a standards setting agency, regularly delegates compliance audits to other parties. For certain tests relating to farm animal eartags and RFID devices, ISO has appointed Service-ICAR as its Registration Authority (RA).

In its experience as the current RA for a number of ISO standards, ICAR believes that the final decision concerning the contracting of the test centres (TC) for the testing of a particular device should ultimately be at the choice of the RA, having heard and paying due regard to the stated preference of the device manufacturer. The reasons why ICAR holds this opinion are summarised below.

- The standards have different levels of tests (e.g. for conformance tests of transponders, “full”, “limited” or “listing update” may be requested). ICAR's experience is that manufacturers do not always know which level of test is applicable to a given product in a given situation. To facilitate the correct choice of test the RA should be the one contracting the test centre.
- In that way it will always be known to the RA when there is an approval test going on, the RA will know exactly where the tested devices for the reference base are kept and it will not cause higher costs for the manufacturers.
- The RA has a base of reference products consisting of all devices tested in all conformance (and performance) tests. The devices are kept in the test centres where the devices were tested. This base enables the RA to retest at any given time if required. It also enables the RA to check if the products in the market are in fact the same as the products tested. Thus the base of tested products is an important tool that can provide answers in case of disputes on the approval and on whether products in the market are in fact identical to the products that received the approval.
- When the manufacturer submits devices to be tested for RA approval the ownership of the devices tested is automatically transferred to the RA. Therefore, a manufacturer can not submit devices to be tested unless it is clear whether it is in fact a RA approval test or not. The RA has to know where all tested devices are kept. All of this will be facilitated by letting the RA contract the test centres chosen.
- There is a potential conflict of interest to have a manufacturer do business directly with a Test Centre for both product development testing and for standards compliance testing. The compliance testing has to be on behalf of the Party In Charge (PIC) which will be the RA. The results

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and certification need to be unbiased for review and use in decision making by appropriate regulatory agencies. This is critical to gain acceptance in multiple countries without large amounts of testing or re-testing.

- The ISO 17025 has rules about protection against other than the customer and the laboratory employees observing or communicating about a test. It is imperative that the RA has the right to do so.
- The decision to approve a device or not lies with the RA. For that reason the test reports should be sent from the test centre to the RA who will then inform the manufacturer.
- If a manufacturer for some reason is not allowed to get an RA approval this might not be known by the test centres. For that reason RA has to contract the test centres.
- Without knowledge of test centre workloads and availability, un-governed choice could lead to excess work or back-logs at a particular laboratory, with consequent delays to the start and conclusion of tests.
- RA has the responsibility to see that all TCs which have RA approval are treated in an equitable manner.
- The RA has to make a list of approved test centres available to the manufacturer. This list must include information about test fees but should in addition inform about time from receiving devices for test till final report and information on the number of tests performed leading to RA approval. The test fees from the laboratories will be commercially driven and the manufacturer may choose which one to use.
- Rather the RA than the TC should make available a web-page where information is given about test fees, test length and reporting for each TC based on their information given periodically to the RA. If this was not the case:
  - there would be a high risk of favouring the test with the lowest cost and limited use of the other TCs.
  - test costs differ from country to country due to factors beyond the control of a TC.
  - when approval or not of a test is with RA it could be misleading for a manufacturer and potentially conflicting afterwards between the TC, RA and manufacturer if a manufacturer chooses the TC based only on TC information only.
- Beside the test fee from the TC there will be also a RA fee to cover the costs of the functions of the RA. The RA fee shall be set by the RA on a cost recovery basis and has to be agreeable for the ISO board according to its directives. The manufacturer will have to pay test fee and RA fee to the RA, but it will be the same amount of money regardless who contracts the test centre.