



Moving from approval to certification for recording and sampling devices by ICAR - a dynamic approach to connect member organizations and manufacturers while encouraging innovation and testing of new devices

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Traditionally, successful ICAR testing of recording and sampling devices results in a lifetime approval from ICAR for the specific device combination. A recording and sampling device may have many components - milk meter, controller, keypad, sampler, firmware, and software. The approval approach has served the milk recording industry well for many devices, particularly mechanical milk meters. However, changes in one or more of the components of a complete device may affect the accuracy of either the milk yield prediction or the delivery of a representative milk sample. While the current ICAR Guidelines state that manufacturers are required to report these changes to the Subcommittee for Recording and Sampling Devices (RSD-SC), some modifications are not reported in a timely fashion. Further, device installation protocols or routine calibration procedures, which are reviewed during the ICAR testing process, may be altered by manufacturers after the ICAR approval is awarded. Validation of these changes by the RSD-SC along with timely communication to ICAR member organizations of such changes has been identified as an area in need of improvement.

The current ICAR Guidelines include language for annual reporting by both device manufacturers and member organizations. Building on these existing reporting Guidelines, the RSD-SC is moving to an annual review of certification for all recording and sampling devices. This dynamic approach is designed to increase the responsiveness of the RSD-SC to member organizations' challenges or concerns as well as facilitate timely resolution by device manufacturers. Further, this certification plan is desirable when compared to re-testing and re-certification of every recording and sampling device after a specific time frame or certification period expires. Rather, manufacturers are encouraged to invest resources into ICAR testing of both modified and new devices rather than in testing of current devices that have not undergone any changes in design or components. This approach to device certification is also expandable to include sensor devices in the future. The RSD-SC is committed to meeting the needs of ICAR member organizations and building strong relationships with device manufacturers.

Keywords: milk recording, recording devices, sampling devices, certification, milk sampling

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Summary

Background and perspective

As one of the standing subcommittees of ICAR, the Recording and Sampling Devices Subcommittee (RSD-SC) is responsible for the testing of milk recording and sampling devices at various ICAR-qualified test centres. Currently these test centres are based in France, Germany and The Netherlands and work cooperatively under the direction of the RSD-SC and Service-ICAR. Testing of devices involves both laboratory and field (farm) testing in accordance with Section 11 of the ICAR Guidelines (<https://www.icar.org/index.php/icar-recording-guidelines>), whose review and maintenance is also the responsibility of the RSD-SC. In addition to testing of the device with respect to specific metrics outlined in the Guidelines, an evaluation of both the installation and routine calibration procedures for the recording and sampling device is conducted. After completion of an ICAR test, a full report of the recording and sampling device is reviewed in detail by the RSD-SC with a resulting recommendation for approval that is forwarded to the ICAR Board for endorsement. Finally, this approval is published on the ICAR website as a reference for all ICAR member organizations.

Traditionally this ICAR 'approval' has been for the lifetime of the recording and sampling device. The RSD-SC does offer the opportunity for device manufacturers to report and apply to modification testing or desk review(s) of changes to devices over time. Some manufacturers embrace this opportunity as modifications or improvements to the originally approved device are brought to the marketplace. Other manufacturers provide only limited updates to the RSD-SC, mostly in response to queries or concerns raised by ICAR members. A lifetime approval for a recording and sampling device is not practical nor in the best interest of ICAR and its members, noting that changes or improvements in devices occur through the normal business practices of device manufacturers. The challenges noted by the RSD-SC include, but are not limited to the following:

- Change in design of meter and/or sampler.
- Change in firmware and/or software.
- Availability of original components.
- Changes or deviations in specific parts.
- Change in installation or routine calibration procedures.
- Quality control issues.
- Change in branding, device name, or mounting position.

Approval versus Certification

While some organizations or businesses may use the terms approval and certification interchangeably, the differences that exist in the application of these terms for positioning in the marketplace are notable. The traditional term 'approved' as used by the RSD-SC denotes that the recording and sampling device has met minimum standards after testing. While in accordance with the specific tests or metrics outlined in the ICAR Guidelines for laboratory and field testing. The term 'certified' is more appropriate in the case of ICAR whose mission involves continuous improvement in systems and practices. Certified or certification implies that not only has the device met minimum testing standards but is also in compliance with all of the ICAR Guidelines including manufacturer reporting and device labelling. Further, certification is a recognition of continued compliance and quality with a specific time frame associated with said certification.



Embracing that the role of ICAR is certification for devices, the ICAR Subcommittee for Animal Identification moved from identification device approval to certification in 2015. This change, as outlined at previous ICAR sessions and on the ICAR website, designates a five-year certification period for an identification device with a specific expiry date. With the goal of maintaining clarity of ICAR certification services for various device categories, the RSD-SC reviewed this approach in the context of retesting and recertification of recording and sampling devices. Noting that the lifespan of these devices is longer and not practical in many situations due to device availability, the RSD-SC concluded that a different approach was warranted. Further, the investment of testing recording and sampling devices made by manufacturers should be focused on new or innovative devices rather than retesting of either current or out of production devices where none of the previously described challenges exist.

Working with existing sections of the ICAR Guidelines and recognizing the needs of ICAR members, the RSD-SC has implemented a dynamic approach to continued certification of recording and sampling devices. It should be noted that no changes to the application or testing of new or modified recording and sampling devices will be implemented. Those processes will continue as described though manufacturers will note potential restructuring of the ICAR Guidelines as part of a larger effort by ICAR to modernize the functionality of all ICAR Guidelines. This dynamic approach was developed using the reporting options that currently exist with a focus on ICAR member engagement and device manufacturer responsibility. The certification of all recording and sampling devices will be reviewed by the RSD-SC on an annual basis. The documentation for this review will be the ICAR member reports and manufacturer reports on ICAR-certified devices in the marketplace. Both of these reports are described in the current ICAR Guidelines. To aid in this reporting, the RSD-SC has developed templates for both groups to complete and submit.

ICAR members are not required to complete an annual report of satisfaction but are strongly encouraged to communicate their concerns to the RSD-SC using this tool. With completion and submission of a member report, the RSD-SC acknowledges a desire for timely resolution to known and relevant issues. In addition to ICAR member reporting on an annual basis, device manufacturers are required to submit a report on ICAR-certified devices in the marketplace. This report will include devices sold and in which countries they are sold, modifications in any and all device components, and alternative market names including private-labelling or branding of said devices.

Using the information provided in the annual reports, the RSD-SC will review all recording and sampling devices for continued certification. For any device with no noted concerns from the member aspect and no reported modifications or changes, ICAR-certification will continue. For those devices that do continue as certified, the RSD-SC will suspend the certification of the device until the concern is resolved. The time frame required for resolution will be at the discretion of the RSD-SC and mutually agreed upon by the manufacturer and the RSD-SC, noting that each case needs to be evaluated on both the merits of concern and scope of the response from the manufacturer. In the case where resolution cannot be achieved, either after attempts by the manufacturer or by the unwillingness of the manufacturer, the certification of that recording and sampling device, including those devices manufactured or marketed under alternative names, will be withdrawn.

As previously noted, certification requires compliance with all the ICAR Guidelines. In addition to the required manufacturer report, a critical component of the Guidelines is labelling of ICAR-certified devices with an appropriate label. This requirement exists

The dynamic approach to recording and sampling device certification



in the current Guidelines (Section 11.5.4 - <https://www.icar.org/index.php/icar-recording-guidelines/>) and will continue moving forward. To aid manufacturers and ICAR members alike, the RSD-SC has redesigned the ICAR label to include device name, year of initial certification, species, and use or mounting position (high-line, low-line or AMS). The application of labels to ICAR-certified devices not only adds value to the device but assists the users of the device in proper installation and use.

The change from lifetime approval of recording and sampling devices to a review and certification process is designed to provide benefits to both ICAR member and device manufacturers. Central to this process is communication between the RSD-SC, building synergy between device manufacturers and device users, resolving issues of concern, and encouraging manufacturers to invest in testing new and innovative devices rather than retesting of devices that have not changed but are currently in the marketplace.