Conclusion

Returning to the main issue of harmonization of EQA/PT providers to use biological variation-based limits and report results in terms of being: “within optimum,” “within desirable,” “within minimum” limits, and “unacceptable” when outside BV-minimum limits (Figure 1).

The BV-based limits provide a more realistic assessment of participants’ performance and corresponding regulatory requirements.

Materials and Methods

Three BV-based limits — optimum (BV-optimum), desirable (BV-desirable) and minimum (BV-minimum) — were established for providers to determine feasibility of using them for establishing harmonized ALPs that link performance to medical needs.

The purpose of this study was to demonstrate a model for harmonization of EQA/PT providers’ practices with use of statistical biological variation data. QMP–LS and CLIA’88 limits were used as assigned values. The robust algorithm described in ISO 13528:2005(E) Annex C (1) was followed for the estimation of all-population based reference interval.

The overall satisfactory result rates using current QMP–LS performance limits (98.3 – 99.9%), CLIA’88 limits (96.3 – 100%) and z-scores (95.6 – 99.9%) were used as the reference limits.

The number of participants per analyte group, total number of participants, and number of participants meeting the analyte specific assignment criteria is shown in Tables 1a and 1b. The number of participants meeting analyte specific assignment criteria was then assigned to the appropriate ALP category. The number of participants assigned to each ALP category was calculated for each analyte and shown in Table 1c. The number of participants per analyte group, total number of participants, and number of participants meeting the analyte specific assignment criteria is shown in Tables 1a and 1b. The number of participants meeting analyte specific assignment criteria was then assigned to the appropriate ALP category. The number of participants assigned to each ALP category was calculated for each analyte and shown in Table 1c.

Results

Our data suggests that current QMP–LS and CLIA’88 limits for the analytes included in this study reflect current state-of-the-art and will be suitable for regulatory purposes.

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