

PROCESS QUALITY ASSOCIATES INC.

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ISO 17025 Needs Assessment

| Line # | Question | Don't Know | Rarely or Never | Sometimes | Usually | Continuously |
|--------|--|------------|-----------------|-----------|---------|--------------|
| | This Needs Assessment assumes that it will be completed by someone with a day-by-day working knowledge of the lab, its methods, its issues, and its customers. | | | | | |
| 1 | Our lab &/or test results are audited/inspected/checked by an outside party (ie. corporate, customer, third party, government). | | | | | |
| 2 | There are significant differences between our lab and the check sample data from other labs (ie. inter-lab validation tests). | | | | | |
| 3 | Someone has to intervene in routine lab work to stop, prevent, or fix problems found or created by others. | | | | | |
| 4 | People get frustrated or worried by our lab's actions, inactions, test results, or methods. | | | | | |
| 5 | People question or complain about the long wait for test results. | | | | | |
| 6 | People question or complain about the high cost of test results. | | | | | |
| 7 | People question or complain about the calibration, accuracy, &/or repeatability of our test results. | | | | | |
| 8 | Our lab avoids promising specific delivery dates & times, or when we promise a specific deadline, we are late. | | | | | |
| 9 | Our lab's work is adversely affected by the hiring, losing, or job satisfaction of competent lab personnel. | | | | | |
| 10 | Other labs use their ISO 17025 or ISO 9001 certification as a selling feature or competitive differentiation against us &/or other labs. | | | | | |
| 11 | The technologies, equipment, or methods in our lab are antiquated and out-of-date, and causes problems for us &/or our customers. | | | | | |
| 12 | Re-investment into our test equipment, methods, & systems is inadequate, or mis-directed by poor prioritization. | | | | | |
| 13 | Our lab makes significant, risky, &/or costly mistakes. | | | | | |
| 14 | We do not fully understand the needs, constraints, & problems of our customers before we start to work. | | | | | |
| 15 | Trust and its violation is a significant issue between our lab and its Stakeholders. | | | | | |
| 16 | Our lab has fallen behind the technical capabilities or breadth of services offered by similar labs. | | | | | |
| 17 | Our EOM (Error of Measurement) is greater than 10% of the acceptable range for the technical specifications of the samples we test. | | | | | |
| 18 | Our EOM (Error of Measurement) is greater than 10% of the range of values for a typical family of samples that we test. | | | | | |
| 19 | There is a problem getting the necessary supplies, reagents, working test equipment, etc. that we need. | | | | | |
| 20 | The lab exceeds its annual operating cost budget, the quoted man-hrs, or budgeted test costs for the various samples being tested. | | | | | |
| 21 | Some Lab Technicians use a different interpretation of the various test methods. | | | | | |
| 22 | Our lab's work is adversely affected (or our risk is significantly increased) by the lack of training/certification of lab personnel. | | | | | |
| 23 | Sr. Management doesn't talk to us about problems, or we are slow to learn and improve from the problems that have occurred. | | | | | |
| 24 | Lab personnel create problems due to their capabilities, predictability, dependability, attendance, or punctuality. | | | | | |
| 25 | There are problems in the lab test methods as to the predictability, dependability, interferences, applicability, selectivity, etc. | | | | | |
| 26 | We have calibration, certification, accuracy, repeatability, stability, linearity, or reproducibility problems. | | | | | |
| 27 | Sub-Total Count the check marks in each column (0 to 26 in each column, totaling 26 for all columns). Copy to Line 28 on Pg. 2 | | | | | |

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|--------|--|------------|-----------------|-----------|---------|--------------|
| | This Needs Assessment assumes that it will be completed by someone with a day-by-day working knowledge of the lab, its methods, its issues, and its customers. | | | | | |
| 28 | Sub-totals carried forward from Line 27 on Page 1 (count will be between 0 to 26 in each column, totaling 26 for all columns) | | | | | |
| 29 | There are problems or lost opportunities caused by ineffective or insufficient team work among lab personnel. | | | | | |
| 30 | There are conflicts of interest between the lab, its customers, or third parties who depend upon the test results. | | | | | |
| 31 | We don't hear praise, recognition, thanks, respect, or complements for the good work that the lab does. | | | | | |
| 32 | Open & honest communication (or its absence) within the lab (or between the lab and its customers) is a significant problem. | | | | | |
| 33 | Our lab's reputation causes significant issues/problems in our on-going success. | | | | | |
| 34 | COUNTS: Count the check marks in each of the 5 columns on the right (0 - 31 per column, total of 31 for all columns) | | | | | |
| 35 | Weights | 20 | 1 | 2 | 5 | 10 |
| 36 | SUB-TOTALS For each of the 5 columns, Multiply each COUNT by its assigned WEIGHT (Line 34 x Line 35) | | | | | |
| 37 | GRAND TOTAL Add all SUB-TOTALS on Line 36 to get GRAND TOTAL (31 questions, with Grand Total between 31 and 620) | | | | | |

| Total | Interpretation: Assuming you truly know what's going on in your lab, |
|-----------|--|
| 31 - 47 | Assuming that you fully understand the questions and what really goes on in the lab, your lab is truly excellent, and a model of efficiency and effectiveness. You are well past mere compliance to ISO 17025, bordering on "business excellence". PQA would be interested in doing a newsletter article on your accomplishments and how you achieved them. No matter how excellent you are, continuous improvement is still important. PQA is interested in aiding your ongoing efforts. |
| 48 - 62 | You have an above-average lab that should be recognized and praised for its achievements. If not already ISO 17025 certified, ISO 17025 certification can help you get all the recognition & success you deserve. Implementation of ISO 17025 can proceed with little discomfort. However, mere compliance to ISO 17025 will probably not fully satisfy your long term goals, and won't provide you with the maximum returns for your efforts. To get the maximum value out of ISO 17025, discuss your plans for Business Excellence and on-going rapid improvement through ISO 17025 with your PQA Consultant. You probably realize that improving at just 1% per day will give you 3,778% improvement by the end of the year? |
| 63 - 109 | The lab generally runs smoothly & effectively, and is well respected. However, there are on-going problems that hurt or limit the lab's success. You will find significant benefits in implementing or reinforcing an ISO 17025 system. The implementation will go smoothly, but will have its challenges and frustrations; requiring some extra effort in the short term. While you could probably do the ISO implementation on your own, there are significant advantages to having an ISO 17025 expert available for guidance or assistance. PQA can turbo-charge the improvement process, and help ensure the end results achieved. |
| 110 - 285 | There is a significant lack of information about the lab and its operations, or a number of chronic issues that are holding the lab back. Either of these situations can create numerous negative consequences for all or most people associated with the lab (both internal to the lab, as well as external). Most likely, these are significant issues that have been avoided or delayed for some time, or the rate of improvement has been inadequate. There are significant gains available through ISO 17025. If improvement isn't started soon, customers will be seeking alternatives on an active basis. Because of the high score, significant work needs to be done, so the ISO 17025 implementation will have significant effort, frustration, costs, and side-effects. You could clearly benefit from expert ISO 17025 implementation assistance. PQA can help facilitate the implementation process; easing you through these difficulties, and get the change process started more quickly & effectively.. |
| 286 - 620 | You have a significant lack of understanding about the lab, its customers, or its issues. You may be distracted by other priorities; or have significant constraints. If you are one of the most knowledgeable, you have serious issues in your lab, some of which are potentially fatal to your lab, or others. You are at unknown risk; the greatest risk of all. Chances are, the lab's customers and other Stakeholders feel the same way about your lab's methods and test results. It is unclear why you are still operating a lab, instead of outsourcing the work to those willing to provide excellence in lab methods and test results. If you insist on continuing to operate your lab, you need ISO 17025 (and/or similar systems) ASAP. Get professional help and assessment of your current situation NOW , before it's too late. As difficult as it may be, PQA can help. |

About PQA PQA (Process Quality Associates Inc.) is a team of specialists that help organizations rapidly improve their quality, productivity, profitability, and stakeholder satisfaction. PQA provides mentoring, coaching, training, consulting, & implementation services around the world to many different industries. For more information on PQA, see our Internet website at <http://pqa.net> For a free, confidential initial consultation, contact PQA in London ON Canada at +1 (519)-667-1720 or email us at pqa@pqa.net