



BABCOCK Laboratories, Inc.
The Standard of Excellence for Over 100 Years

September 15, 2016

Ms. Felicia Marcus, Chair
Members of the SWRCB

Honorable Chair & Members of the Board,



As the Chief Executive of a California Small Business, I am deeply concerned about the cost of conducting business in California and as a member of the commercial environmental laboratory community, I **strongly object** to the ELAP fee increase under consideration by the Board. As proposed, the 2017 fee adjustment will increase the base and Field of Testing fees by approximately 25 percent. I argue that CA ELAP should not burden California laboratories with a 25 percent fee increase in 2017, and provide support for this claim in this letter to the Board.

First and foremost, the proposed fee increase—which must be viewed as an additional fee increase, given the recent fee increase of 57.84 percent—does not abide by the recommendations given by the Expert Review Panel (ERP) to CA ELAP. In its final report, the ERP strongly advised, “that ELAP develop a new fee structure that improves fairness of the cost burden” and one that is “based on three functions: assessment, accreditation maintenance (e.g., PT evaluation, application processing, adding scope without assessments), and compliance assessments for significant issues or cause.” This additional fee increase of 25 percent places undue cost burden on CA accredited laboratories.

Second, the fees for laboratory accreditation under CA ELAP already increased by 57.84 percent this year, with no real improvement to services currently available to the laboratories. CA ELAP services are still demonstrably substandard because the program has just begun the lengthy and challenging process of changing its systems, implementing a new standard, and, perhaps most importantly, training its unprepared staff.

The 57.84 percent increase implemented this year has had a significant financial impact on our small commercial laboratory. Under the last increase, our CA ELAP fees grew from \$8,303 to \$13,105, and because California cannot currently provide our small commercial lab with credible, widely-recognized laboratory certification, we have also been burdened with paying an additional \$12,453 (plus auditor travel expenses) to the Oregon ELAP for accreditation to the National Laboratory Accreditation Program (NELAP) Standard. Under the across the board fees increase already implemented by CA ELAP this year, our fee costs have tripled. An additional 25 percent fee increase will add further financial burden to our laboratory and its staff, particularly given that CA ELAP cannot, in the foreseeable future, meet most if not all of our needs.

Which brings me to my third point, which is that many California laboratories are still forced to pay other accrediting fees because the State is no longer a nationally recognized Accreditation Body (AB). Most private sector laboratories operating in California require accreditation services that ELAP cannot provide because the program currently lacks the qualifications, functionality, and systems defined as requirements in international standards of practice for ABs. Commercial laboratories require recognized, standard-conforming ABs to assess their laboratory’s conformity



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with national and international standards of practice. The proposed fee increase presents an additional financial burden to commercial laboratories like mine by compelling us to pay for ELAP assessment services that do not meet our needs while also paying for recognized, standard-conforming ABs to provide the assessment services necessary to allow us access to national and international markets for our services. Just as with the 57.84 percent increase, the proposed additional across-the-board 25 percent fee increase is not equitable for labs with multiple Fields of Testing (FOTs) who pay more but receive less.

Finally, CA ELAP has not seriously considered alternatives, such as the separation of licensure and accreditation services and the utilization of nongovernmental ABs. This solution would reduce cost, increase efficiency, and produce data of known and documented quality.

Cost

This solution offers significant cost savings for both CA ELAP and CA accredited laboratories. First, the costs required to train and manage staff, implement new systems, and adhere to a new standard—all of which is required to provide competent laboratory accreditation services—is substantially greater than the costs required to provide competent laboratory licensure services.

Moreover, CA ELAP should seriously consider the separation of licensure and accreditation services to allow the fees for licensure services to reflect the maximum of 4 hours of clerical staff time required to issue a laboratory license based on reports provided by recognized third party ABs. This is fair and equitable to the laboratories because it allows them to use ABs that meet their CA ELAP needs, in addition to their other accrediting needs, and for a lower price.

Laboratories need the option to select AB services that meet their needs and provide value that is equivalent to the fee. Nongovernmental ABs are market motivated to provide high quality services at fees commensurate with the value provided.

Efficiency

State separation of licensure and accreditation services and the utilization of non-governmental ABs has already demonstrated itself to be more efficient. The State of Florida is a proven and successful model of how the State can delegate the bulk of the laboratory review process to third party ABs while retaining the licensure decision and oversight of the program.

In order to be recognized, nongovernmental, third party accrediting bodies must meet and abide by nationally recognized systems and technical standards. These ABs are already in operation and do not require the system changes or staff training that CA ELAP requires. Moreover, most commercial laboratories are already paying fees to these ABs to receive the national accreditation that CA ELAP cannot (and has no plans to) provide. For these reasons, utilizing nongovernmental, third party ABs is clearly more efficient than restricting accreditation services to CA ELAP staff.

The current fee structure lacks a “license fee” for laboratories that are assessed by recognized ABs that are functioning at a higher level than that of ELAP’s current capabilities. License fees should be set at levels that fairly reflect the commercial labs’ obligations to support California’s laboratory regulatory program, while fairly reflecting the order of magnitude lower costs of providing licensing services relative to the staffing, training, travel, and organizing costs

involved in providing onsite laboratory assessment services. The separation of fees for ELAP's provision of licensing and AB services is a necessary injection of fairness into a system that is highly unfair to California small laboratory businesses like mine.

Quality

The separation of licensure and accreditation services and the utilization of nongovernmental ABs would also help ensure greater quality. High fees with low value and with no option to select alternative, demonstrably better services, does not allow the laboratory community to improve, and instead stifles lab improvement and limits it only to the expectation of low value service instead of the higher expectation provided by agile, market-driven continuous change and improvement.

The benchmarking method—comparing services to nongovernmental, third party ABs—for assessing fees relative to value is more rational, and demonstrably fairer to ELAP customers than what appears to be a simplistic assessment of fees based on ELAP's operational costs for the provision of incomplete AB services. At this time, ELAP fees cannot be assessed relative to value since the program has not been fully established and implemented.

The decision not to seriously consider alternatives, such as the separation of licensure and accreditation services and the utilization of nongovernmental ABs, will support the American Council of Independent Laboratories' stated concern, "that a government agency appears to set user fees to support continued ineffectiveness justified by an unnecessary monopoly to operate an AB granted by the state legislature." I am confident that this is not the intention of CA ELAP or the State Water Resources Control Board.

In summary, there are many reasons CA ELAP should not burden California laboratories with a 25 percent fee increase in 2017. The proposed fee increase does not abide by the recommendations given by the Expert Review Panel (ERP) to CA ELAP. Further, CA ELAP already increased the fees for laboratory accreditation by 57.84 percent this year, with no real improvement to services currently available to the laboratories. It remains troubling that the California fee increase is several years ahead of any substantive improvement in the CA Lab Accreditation Program. Additionally, many California laboratories are still forced to pay other accrediting fees because the State is no longer a nationally recognized Accreditation Body (AB). Finally, CA ELAP has not seriously considered alternatives, such as the separation of licensure and accreditation services and the utilization of nongovernmental ABs. CA ELAP must look at working solutions that would reduce cost, increase efficiency, and produce data of known and documented quality.

In conclusion, I urge you to reconsider adoption of the CA ELAP fee increase.

Sincerely,



Allison Mackenzie
Chief Executive Officer
Babcock Laboratories, Inc.