Fresh

VOLUME 15, March 2010
INDIA ANALYTICAL SCIENCES

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E D I T O R I A L

Dear Readers,

After two editions of Fresh in the New Year, we are overwhelmed by the positive response we have gotten from you – the reader and our most important critic.

Apart from the generous comments about the new shift in direction of Fresh, several of you have asked why we are focusing a lot on test labs and their impact on us.

The way we see it, the world is changing at a dramatic rapid pace. Gone are the days when people only thought of analytical and scientific equipment are to be for the scientific community and academicians alone. While that may be true from a technical standpoint, there are a lot of people out there who might not be from the scientific community but do appreciate technology at its highest level. What's even becoming more satisfying for these people is to know where this technology is now finding a place in, and how it impacts their lives. While they are convinced that these high-end equipments find a strong place in laboratories, they are now starting to understand the very purpose behind them – and if it can be used to detect how good that glass of water really is, or whether that toy truck is to be played by their child – then why not spread the awareness!

Another comment we generally receive is the shift from technical to, well, less-technical!
We here at PerkinElmer believe that technology should not only be made available to all, but also understood in plain layman's speak. And the only way for people to truly appreciate that, is to make the articles both interesting and easy-to-comprehend for all. That is why Fresh now carries articles that can benefit, let's say, the scientist and the purchase officer – different backgrounds, but common interest! Let's face it, if technology was for the privileged few, only research scientists would carry i-Pods!

And moving with that trend, we will carry in this edition the need for Independent Test labs, thereby bringing an end to our three month focus of the testing laboratories. We will also cover a very critical issue for most lab managers – managing the assets.

WHAT'S Fresh inside...

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Independent Labs – A Better Alternative?

Independent labs are a service industry that provides answers or verification of answers in an evolving and increasingly complex world. A loose definition of an independent laboratory is a person or group that provides independent verification or testing to identify something, determine performance characteristics, or confirm attainment of specifications. Reasons why an independent laboratory is used include:

1. In-house capabilities are unavailable
2. Results are needed faster than can be accomplished with internal capabilities
3. Independent analysis is required by customer or government
4. Confirmation of internal findings is needed

The decision to use an independent lab is based on financial, technical, and/or regulatory points. Deciding which lab to use is based on that lab's ability to service the customer's needs and the relationship the lab builds with the customer.

Evolution of independent labs

The evolution of independent laboratories in many ways follows the course of man's evolution. Testing has always been a component of the scientific process. The caveman that first captured fire and tested his invention by sticking his hand in it, and the clan in the next cave that confirmed that fire burns but can also be used as a tool for survival, are similar to the inventor or corporation that develops a product and the independent lab that confirms the material or performance specification. Initially, and in some cases still to this day, the consumer is the ultimate independent lab, although unwittingly at times.

As man evolved, the thinking and questions grew more complex. The questions grew even more complex with the aid of accountants, lawyers and, of course, the government. The inventors/corporations began asking: Does this fill a need, and what are its limitations? Does the product meet the customer's specifications? Will the product hurt the consumer or the environment? How do we improve the product? Why is our competitor's product better? How do we protect our intellectual property? Is our competitor infringing on our patent? The consumers began asking: Did we receive what we paid for? If the component we bought meets specifications, why is our product failing? Could this product be the cause of a problem? The need to answer these questions before the product reached the end user, led to the growth of independent labs. And the primary driving force for the need for independent labs today is the cost of answering all these questions.

While some testing, such as process

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quality control, is still best performed in-house, the cost of adding the equipment and technical staff to answer varied and changing questions may not make financial sense to the inventor/corporation. Business philosophy has also changed from a focus on fully integrated systems to a focus on core competencies and the use of competent contractors. Also, trust is not always a given in human interactions, and lack of trust creates the opportunity for an independent lab to act as an impartial third party acceptable to both sides of the issue.

Challenges to independent labs

The ability to service these needs presents some unique and not-so-unique business challenges to an independent lab. An independent lab has the same financial needs as any business: to balance the breadth of capabilities required to meet the majority of the market needs, control costs, and provide a return on investment. As with any service business, the quality of the product (in this case the data), the ability to meet time lines, communication with the customer, protection of confidentiality, and any value-added services define the lab and determine its success as a business.

One unique management challenge is staff selection. While the quality of the data must be unimpeachable, the ability to communicate with and understand customer needs before, during, and after delivery is not always the forte of technically oriented scientists and engineers, but it is just as important to the success of the independent lab. In addition, the technical staff needs to fit the type of testing performed by the laboratory. The repetitive, high-throughput testing

performed at many independent laboratories requires the right individuals to perform the tests with the same quality over time. Project-based laboratories need staff who can change focus and grasp the quality and technical needs quickly. Many labs may have both activities and require just the right mix of staff. In all cases, the combination of technical expertise and the ability to multitask, listen, and communicate is essential.

Another unique management aspect for independent labs is the selection of markets. As with most businesses, independent labs need to know their core competencies, markets, and limitations. The equipment and staff may have capabilities over a variety of markets, but customer needs may vary widely, making it difficult for the business to be successful across multiple market segments. An example would be environmental chromatography and pharmaceutical chromatography. The instrumentation and techniques are similar, but the documentation and performance requirements for each market are quite different. At the same time, knowledge of closely related markets and the ability to serve them may become an advantage or a necessity if one's primary market has a downturn.

Independent labs can be found servicing just about every industry. Some service a specific industry, such as consumer products, automotive, aerospace, pharmaceutical, food, or agriculture. Others may cover a material, such as petroleum, plastics, rubber, coatings, or metals, over several industries or in a specific niche such as fuels, lubricants, or plastic medical devices. Still others may focus on a type of testing, as in environmental, electrical, fire, or acoustical performance.

Independent labs often have some form of accreditation. The accreditation may be a requirement for some customers and markets and may help a lab acquire new business. Unfortunately, the cost and time it takes to add new methods to the scope of accreditation tends to limit the responsiveness of the lab to changing customer needs. In some cases, the lab may be able to perform an inter-laboratory study or gauge R&R study with the customer's internal lab to demonstrate capability, instead of or along with accreditation activities. Accreditation can also increase the cost to enter and therefore limit entry into a market. Starting a new lab in a market requiring accreditation may require additional financing to carry the business for several months or even a year or more until accreditation can be completed.

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Academic and in-house labs

Independent labs may seem to compete with academic and in-house industrial laboratories, but in reality, they fill a different role and may even work with other labs. The academic labs often have unique capabilities that cannot be found routinely in the commercial market. Although they may have routine testing capabilities, their service profile is usually different from that of a commercial independent lab. Some states legally limit them from competing with commercial entities. Typically, the commercial independent labs have the advantage in service and accreditation.

When a company outsources testing, industrial labs may feel that independent labs are competing with or taking away their work. However, there are areas of testing that are best performed by an in-house lab and some that are better performed by an independent lab.

Sometimes researchers perform their own testing within an industrial lab. However, depending on the circumstances, it may be more efficient to have an independent lab perform the tests and free up the research staff to concentrate on new product development.

Independent labs are sometimes developed from inhouse industrial labs to leverage the investment in the equipment and staff. In most cases, the lab is set up as a separate entity to ensure separation for confidentiality while still allowing support for the parent company's testing needs. This is a particularly unique challenge, depending on the structure of the lab prior to separation and the need to develop new systems prior to or immediately following launch. Excellent document controls, access control, and education of the staff on maintenance of confidentiality are critical to making customers, sometimes including former competitors, feel comfortable using the lab's services.

In the current down economy, there are opportunities for and threats to independent labs. An independent lab can fill the testing needs of companies experiencing cutbacks in internal capabilities or deciding to outsource their testing. However, if the lab is positioned in a down market segment, the lab may need to make its own business decisions on cutbacks or re-position to work in other market areas.

As mentioned earlier, independent labs are a service business that thrives on the need to perform quality testing services to answer a variety of customer questions. Successful labs protect their customers' confidentiality; meet their time lines; act as the independent third party; and build relationships based on service, trust, and anticipation of the customers' needs.

As a result, independent labs fill a need in the market. There is a need for all three types of labs. Some of the most successful companies use independent labs as well as in-house and academic labs to further their success. Take a look at the independent labs that service your industry. If you are not using one already, you may want to take a closer look and start building a relationship with one or more. There may come a time when you need their service to answer a question, and a good independent lab may make all the difference.

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Analysis of Micronutrients in Soil by Using AA 800 Atomic Absorption Spectrophotometer

Editor: Praveen Sarojam, Ph.D

Soil is used in agriculture, where it serves as the primary nutrient base for plants. Soil resources are critical to the environment, as well as to food and fiber production. Waste management often has a soil component. Land degradation is a human-induced or natural process which impairs the capacity of land to function. Soils are the critical component in land degradation when it involves acidification, contamination etc. Soil contamination at low levels is often within soil capacity to treat and assimilate. Many waste treatment processes rely on this treatment capacity. Exceeding treatment capacity can damage soil biota and limit soil function. Derelict soils occur where industrial contamination or other development activity damages the .soil to such a degree that the land cannot be used safely or productively. The analysis of soils is an excellent measure of soil fertility. It is a very inexpensive way of maintaining good plant health and maximum crop productivity. The standard soil test provides the status of potassium (K), calcium (Ca), magnesium (Mg), pH, cation exchange capacity, lime requirement index, and base saturation. Additional tests are also available for iron (Fe), zinc (Zn), manganese (Mn), soluble salts, and nitrates. Soil fertility fluctuates throughout the growing season each year. The quantity and availability of mineral nutrients are altered by the addition of fertilizers, manure, compost, mulch, and lime or sulfur, in addition to leaching. Furthermore, large quantities of mineral nutrients are removed from soils as a result of plant growth and development, and the harvesting of crops. The analysis of soils will determine the current fertility status. It also provides the necessary information needed to maintain the optimum fertility year after year. In the present work we compare the performance of Mehlich-I extraction with that of microwave digestion for the determination of several micronutrients in soil samples.

Experimental

The measurements were performed using the PerkinElmer® AAnalyst™ 800 atomic absorption spectrophotometer (PerkinElmer, Inc., Shelton, CT, USA) equipped with WinLab32™ for AA Version 6.5 software, which features all the tools needed to analyze samples, report and archive data and ensure regulatory compliance. A PerkinElmer Multiwave™ 3000 microwave oven was used for the microwave-assisted digestion of soil samples. This is an industrial-type oven which can be equipped with various accessories to optimize the sample digestion.

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Sample preparation

Representative soil samples were collected from three different locations and were finely ground and then passed through a 20 mesh sieve to obtain very fine particles. 5.0 g of an air-dried, ground and sieved sample was placed in an Erlenmeyer flask and 20 mL of the extracting solution (0.05 N HCl + 0.025 N H2SO4) was added to it. Then it was placed in a magnetic stirrer and the mixture was stirred for 20 minutes. The resulting solution was filtered through a Whatman® No 42 filter paper into a 50 mL polypropylene vial and diluted to 50 mL with the extracting solution. The analytical reagent blanks were also prepared and these contained only the acids. The above mentioned procedure is in accordance with Mehlich-I extraction. The microwave digestion of soil samples were done in accordance with EPA Method 3052. This method is applicable to the microwave assisted acid digestion of siliceous matrices, organic matrices and other complex matrices.

Results and discussion

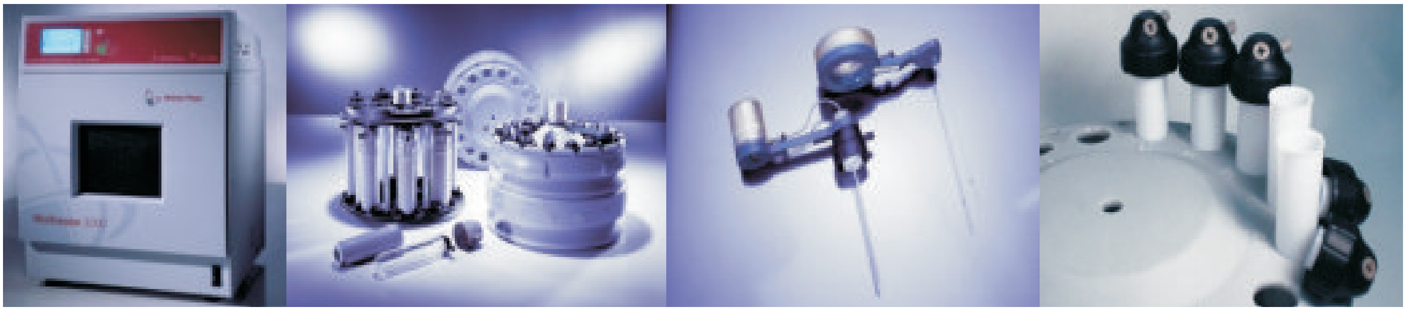
The Mehlich-I extraction will give an indication about the amount of extractable micronutrients in soils. If one needs to know the total metal content, complete decomposition of samples with a microwave digestion is the preferred choice. The ability of PerkinElmer/Anton-Paar Multiwave 3000 microwave digestion system to digest the soil samples in accordance with EPA Method 3052 was demonstrated. The method detection limits obtained indicates that the reliable analysis of micronutrients in difficult matrices such as soil samples is possible with the AAnalyst 800 atomic absorption spectrophotometer. The analysis of reference materials and excellent spike recovery results gave further proof to the accuracy of the developed method.

Results of Soil Certified Reference Material (from High Purity Standards) analysis and Method detection Limits (MDL)

Metal	Certified Value (µg/mL)	% Recovery in Solution (in HCl and H_2SO_4)	% Recovery in Solution (in HNO_3)
Cu	0.30	103.2	104.1
Fe	200.0	95.2	96.6
Mg	70.0	98.1	98.1
Zn	1.0	105.7	100.7
Na	70.0	105.6	98.4
K	200.0	95.4	95.4
Mn	0.10	103.5	102.7

Metal	MDL (Mg/Kg)
Cu	0.08
Fe	0.31
Mg	0.009
Zn	0.013
Na	0.02
K	0.02
Mn	0.04

Detailed Application note can be viewed at
http://www.perkinelmerapplications.com/VOL_02/index.html



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Protecting your assets!

Although of central importance to lab operations, capital assets are typically managed as a series of ad hoc activities drawing extra attention only when circumstances bring issues to the forefront. Critical elements such as instrument maintenance are certainly systematized and actively managed, but few managers have considered asset management as an integrated function and some don't appreciate the full scope of this responsibility. As a result, management styles tend to be reactive and piecemeal which implies that this may be a fertile area to explore for improvement opportunities. Asset management is not a familiar term within the context of laboratory operations. Therefore, the first step toward improvement is to establish boundaries and limits on the elements included in the function with at least a general explanation of the management roles encompassed. A little reflection on the performance expectations for lab managers might suggest that the following elements could reasonably be included in asset management:

- Capital Planning
- Capital Acquisition
- Maintenance
- Quality
- Regulatory/Accreditation Compliance
- Disaster Recovery

These are familiar functions within the realm of responsibility of laboratory managers but are rarely considered as part of the same performance dimension. It is instructive to examine the management expectations that go with each of these functions to gain an appreciation for the scope of the responsibility and to identify areas where new improvement opportunities might lie.

Capital planning

Capital planning management involves three activities — capacity management, re-deployment strategy, and retirement/obsolescence decisions. Capacity management refers to the process of assignment and scheduling of work to take full advantage of each instrument so that the lab realizes the maximum benefit from its assets. This includes an ancillary responsibility for monitoring usage rates as a feed into the capital cycle for timing the introduction of additional capacity when needed. Since analyst labor is usually the limiting resource determining utilization rates, capacity optimization is generally addressed in the human resource and workflow management issues that dominate a lab manager's attention. However, the connection into the capital cycle is more loosely managed which can result in operational bottlenecks if staff members fail to inform the manager until instrument limits are reached. Without active monitoring, the lab manager might not have sufficient time to introduce an additional instrument into the capital cycle or might lack appropriate data for economic justification to shepherd the request through the approval process.

In addition to planning for capacity expansion, effective management identifies under-utilized assets for redeployment to other labs or other parts of the organization where they can derive greater value for the business. In cases where redeployment is not an option, the strategy might be to lower the cost of ownership by adjusting maintenance schedules to more closely match the utilization level. That is, if the equipment is underutilized, preventive maintenance is likely performed more frequently than necessary so that the interval between services can be lengthened to save labor and material costs. Also, under-utilized equipment might signal an outsourcing opportunity.

The last portion of capital planning is management of equipment obsolescence and retirement. There are several critical factors to monitor to guide these decisions — condition of the equipment, timing of the capital cycle, state of the technological, criticality of the equipment, and economic cycle. Rising maintenance costs foretell the end of the useful life of an instrument as the increased cost of ownership begins to exceed its benefit. Managers must be alerted at the appropriate time in order to enter replacement equipment into the capital cycle so that approved budget is available before the equipment fails. Timing is especially important for critical equipment since the replacement cycle can take over a year from start to finish. The manager must also be aware of technological advances that might warrant replacement before the end of the useful life of the equipment. For example, some improvements in sensitivity or automation yield such significant increases in productivity that it is more cost effective to dispose of even partially depreciated fully useable equipment than to forego the new technologies. And, of course, the phase of the economic cycle for the particular industry determines availability of capital funds which must be factored into capital planning management.

Acquisition

Some lab managers end their involvement in the capital cycle by delegating acquisition to the scientists once they obtain the financing approval. However, managers have a fiduciary responsibility to see that the appropriated funds are used wisely and in accordance with business goals. This requires some oversight of the actual

buying cycle and is not a trivial task. Due diligence in purchasing requires an investment in time and resources to manage risk and obtain the most value for the money. Many chemists have preconceived ideas or preferences for specific brands of instruments and will skip the thorough analysis embodied in the buying cycle if permitted. Wise asset management asks that decisions pass through the rigor of the entire process to confirm that the preferred instrument is indeed the best choice to bring the organization the most benefit for its investment. The process also provides the best opportunity to embed service options such as guaranteed response times or software upgrades at the point where these concessions are more likely to be granted by the vendors. Experience has shown that competitive market comparisons can often lower the capital investment.

Maintenance

Maintenance is the most familiar of the asset management tasks and typically is the function that receives the most attention from the lab manager. The two areas of responsibility are preventative maintenance aimed at preserving function of the asset and repair aimed at restoring function. As one of the most costly items in the typical laboratory budget, this function has received some attention so that more advanced models have evolved to streamline management and introduce more efficient operations. The management philosophies surrounding laboratory maintenance have already been described in some detail3 so that the specifics will not be rehashed here. Suffice it to say that considerable opportunities for improved productivity and efficiency remain for most lab managers and this remains a fertile area for investigation by those labs facing cost reduction mandates.

Quality

The laboratory quality system encompasses virtually all aspects of operations and imposes responsibility for execution directly on management. Naturally, these responsibilities touch asset management, primarily in two areas — validation and calibration. The first responsibility, validation, means that each asset must be proven to be fit for its intended purpose by objective evidence. This responsibility goes beyond merely verifying that instruments meet manufacturer's specifications as is done during the buying cycle but requires the additional step of proving capability of delivering data at the precision required for each method assigned to the instrument. This can range from a relatively simple procedure in unregulated basic chemical or petrochemical labs to a very complex task requiring special expertise for regulated industries such as pharmaceuticals.

The second quality element, calibration, falls into the core competency of a test laboratory so that virtually all have well developed reliable systems. While oversight responsibility is clearly within the management sphere, failures in this area are so intolerable that accountability is shared by the entire staff. Issues typically arise only when external contractors are used and there are no management controls in place to insure that the work is done properly. Simply requiring certificates or other documentation is no guarantee that calibrations are actually performed correctly — good asset management practice requires performance based acceptance criteria based on replication of results for standard reference or monitor samples.

Regulatory/accreditation

Regulatory requirements touch asset management primarily through the documentation system. Compliance requires rigorous recording of all activities associated with use and maintenance of quality critical assets as well as QC data proving instrument performance. Thus, management of assets requires the establishment of a systematic method for collecting required information plus periodic audits to insure that the system is being properly used and maintained by the staff.

Accreditation requirements impose an additional onus on calibration and maintenance systems for assets that fall within the scope of the quality system. For example, the laboratory may be required to use only accredited vendors for servicing these assets which limits choices, raises costs, and imposes additional documentation requirements. Even when services are performed by internal personnel, there are additional requirements such as construction of uncertainty budgets, traceability of standards, and proof of the competency of the technician. While the management bureaucracy surrounding the regulatory and accreditation requirements associated with each asset is often regarded as a nuisance, it can become even more time consuming and expensive when it is not seriously followed.

Disaster recovery

Within any lab, there is some risk of loss of critical assets due to accidents or gross equipment failures. For those labs supporting an industrial operation such as a large chemical plant, plans must be in place to quickly restore service to avoid significant economic loss. Options might include switching critical tests to backup instruments, using a contract lab, obtaining temporary mobile lab facilities, locating critical equipment in unit control rooms, or similar tactics. Typically these plans also consider reduced testing schedules and general paths to restoring full functionality of the lab. The main point of the plan is to identify these contingencies beforehand in order to restore function in the shortest possible time.

Conclusion

Effective system management can yield significant benefits for a laboratory as illustrated by the efficiencies and cost savings in maintenance operations. When the same systematic approach is expanded to encompass all of the activities surrounding management of capital assets, even more benefits can be realized. As lab managers are pressed to control costs, this is an area worth looking at for productivity gains.

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What's happening at PerkinElmer

Launch of the new PerkinElmer Health Sciences facility in Chennai – **India's first Maternal, Fetal and Newborn Health Laboratory**

On the 17th of February 2010, PerkinElmer launched their new Genetic Screening facility in Chennai under the name PerkinElmer Health Sciences. Keeping in line with PerkinElmer's For The Better belief, the new facility promises Healthier Pregnancies, Healthy Babies and Healthy Families.

During the event, Professor Kypros Nicolaides had accredited MediScan as the official Fetal Medicine Foundation (FMF) training center in India.

The event was graced by the honourable deputy chief minister of Tamil Nadu Thiru M. K. Stalin and was accompanied by his wife Mrs. Durga Stalin.

The event was also attended by Dr. Rekha Ramchandran, president of Down Syndrome Society of India.

Other distinguished guests included Dr. Suresh from MediScan, Dr. Fedja Bobanovic, Scott Palubiak, Yvonne Parker, Bill McKenzie and Subhamoy Dastidar, all from PerkinElmer.

PerkinElmer Hyderabad has found a new home!

To cater to our ever increasing demand from our customer in Andhra Pradesh, we have now shifted our offices to a brand new location – the enviable Raheja Mindspace at Madhapur.

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