A Measured Approach to the Assessment of Quality in Electron Microscopy Labs


INTRODUCTION
This paper follows on from a previous paper by the authors on “Quality in Electron Microscopy” [3] and addresses the need for a measurement system. It questions whether electron microscope laboratories function to a recognised quality performance level on a daily basis, compared to a theoretically optimised standard, and suggests that better quality results may be obtained by following a predetermined set of formal activities.

To establish what the current general performance level is, a survey was conducted with electron microscope laboratories using a self-rating questionnaire and these results were analysed and discussed. Conclusions are then drawn as to how electron microscope laboratories may change their approach to quality in order to optimise performance.

BACKGROUND
The cost of equipping an electron microscope laboratory with state-of-the-art instruments and then maintaining them at a high level is becoming prohibitive for many institutions. This phenomenon is particularly true of electron microscope facilities based in educational institutions. Thus, pressure is placed on the laboratory to offer its services commercially. The measures described within this paper should easily be applied and maintained by a laboratory manager or senior person.

METHODS
It is our view that a numerical rating approach to judging the procedures and standards of a laboratory offers the only solution towards a consistent approach to quality and an improvement in those standards. The system outlined is based on the well-known ISO 9001 standard and broader total quality management principles. To help identify the level of quality achieved within a laboratory, a series of task identifiers with a rating scale (0-5) was set down. The system allows the laboratory to judge their current level of achievement and to see a way forward to quality improvement. Following a survey of 32 labs with a potential score of 300, the average score for an educational establishment was 52.69 versus 74.33 for a non-educational establishment.

KEYWORDS
electron microscope laboratory, standards, quality control, procedure evaluation, preventive maintenance procedures

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The Questionnaire

The questionnaire contained the following questions:

LS1. Do you retain your staff and do you rely upon students working under supervision to perform work for those outside the unit?
LS2. Do you have a laboratory quality policy, a plan of action, and how good are your policy and staff management structures?
LS3. Is there confirmation of laboratory actions matching written procedures – auditing?
LS4. Do you have a level of internal or external certification?
PM1. How often are you able to perform a task when it is presented to you?
PM2. Do you have laboratory-wide targets for improvement and implementation of written standards for micrographs and EDS results?
PM3. Do you set targets for new projects and do you have target indices and timing for each project?
PM4. Do you have specific actions applicable when the results are sub-standard?
INS1. Do you have basic written instructions in the operation of each piece of equipment?
INS2. Do your instructions include advice on operating variables?
INS3. Are checks carried out on the microscopes?
INS4. Is the equipment serviced by experienced personnel?
INS5. Is the equipment regularly calibrated?
INS6. Do you have a procedure for carrying out the tasks in INS3 to INS5?
INS7. Do you keep inspection records on your equipment?
INS8. Do you have procedures for handling item purchases?
ST1. Do you have training programmes for staff and internal supervisors?
ST2. Do you check the ability of your staff to operate the preparation equipment, microscopes and associated analytical equipment; do you know their limits of performance?
SAF1. Do you employ risk assessments within the laboratory?
SAF2. Do you make a full assessment of the chemicals used within the laboratory?
LC1. Are you using a computerised ordering and tracking system?
LC2. Are you keeping a record of all purchases for back-up?
LC3. Are you using a system that allows you to track all items purchased?
PM2. Do you have laboratory-wide targets for improvement and implementation of written standards for micrographs and EDS results?
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equipment is faulty, staff must consider the consequences of that fault on the measurements taken by customers whilst using the equipment since the last time the staff knew it was satisfactory. This may mean that staff have to recall results, or it may mean that no action is required. Either way they should formally consider the matter and record the consideration and decision.

A ‘concerns log’ should reside along with every piece of equipment in the laboratory. This book should be viewed on a daily basis and any concerns rectified; that may mean making contact with the service organisation. Whether serviced by an external contractor or by internal staff, a service report should be provided and filed. After a major service the service staff should produce micrographs to display the instrument condition. All maintenance data should be correlated and held on a database for future reference and for guidance in future corrective actions. A control plan should be developed for the PMP, documenting service procedures, standard tests and advised service intervals.

Each instrument may require certain supplies to be available at all times. Each component should be labelled as to which instrument it is associated, along with the part number, supplier details, cost, delivery time, an alternative supplier, minimum stock level and reorder quantity. In a similar fashion, preparation materials, chemicals and laboratory consumables should be correlated to ease stock control and re-ordering.

Staff Training

Developing training schemes for laboratory staff is an essential part of quality improvement. Laboratories should ensure that they have staff that are adequately trained or experienced in the tasks being accomplished. Senior staff must identify the skills required for the tasks that affect quality, provide training, evaluate its effectiveness, ensure staff are made aware of the importance of their tasks, and keep records of the training and staff experience.

For most tasks, training by internal staff may be sufficient. External courses are of partial use, but practical courses on your own equipment in your own laboratory are invaluable for training the operator in the quirks of the particular instrument and for improving productivity and the quality of results. It is important for staff to appreciate methods of specimen preparation and instrument operation that may be used in other laboratories, thus broadening their view on a subject. It is just as important in a quality regime to develop new specimen preparation techniques and operating procedures as it is to have a firm grounding in the base subject.

Many tests are carried out in electron microscope laboratories to check the instrumentation but few check on the abilities of those that use the instrumentation. To set and obtain a high standard for results requires an understanding of each operator’s capabilities and any shortfall should be taken into account when training is planned.

Safety Procedures

Those who supervise others within a laboratory environment have a ‘duty of care’ and unless continued risk assessment is practised, that duty is not being fulfilled. Different countries have their own risk-assessment criteria, all of which should cover the equipment and chemicals used within the laboratory and the methods used to inform the staff of the possible dangers.

All assessments should include an area for possible improvement that, in turn, should be placed before a laboratory meeting for further discussion in relation to possible implementation.

Q U E S T I O N N A I R E R E S U L T S A N D D I S C U S S I O N

A survey was carried out to assess the potential of the points system in typical electron microscope laboratories. In order to retain confidentiality in relation to the survey sources a third party was used to filter the data such that only the nature of the laboratory and the survey results were passed to the authors.

Information was obtained from 32 laboratories in Australia, New Zealand, South Africa, the United Kingdom and the United States. This information was broken down into two divisions: educational and non-educational establishments.

Figure 3 indicates the average performance of 4 points in each group is a level that laboratories should attain if they were in a competitive environment.

Taking all the data surveyed into consideration, with a potential score of 100 the average points score for an educational establishment was 52.69; from a non-educational establishment the average was 74.33. The highest score was 92 and the lowest 28. For non-educational establishments their highest score was 82 and their lowest 66.

In all areas surveyed non-educational establishments outperformed educational establishments. This result is certainly due to their accreditation through trade or government bodies that carry out audits that conformed to industry or ISO standards.

The only area of the survey where the two applications came close in performance was that of safety, where local government regulations almost certainly made safety a legal requirement. The topic of training in both cases proved to be one where they most underperformed. In educational establishments the two topics of laboratory staff and staff training provided surprisingly poor results and indicate a need for these bodies to reassess their actions in these areas. Greater overall efficiency could be achieved by setting better laboratory policies and in auditing and improving the staff training procedures.

C O N C L U S I O N S

Adopting a numerical evaluation of a laboratory against a formal criterion will set standards for both the small and the large to achieve. The laboratory will know what quality level they have achieved and what they could achieve. In general, one would expect a raising of standards when an honest appraisal is made. For those who control finance, a regular appraisal would provide a far better view of a laboratory cost performance and most of all a laboratory’s ability or inclination to improve its viability.

There may be standard explanations for not conforming to a task schedule, such as operational documentation stifles innovation. However careful study of the tasks should bring the reader to the understanding that the observations made are actually common sense in a well-run laboratory.

R E F E R E N C E S


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