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8.1 The approach to quality

Measurements, whether biological, chemical or physical in nature, affect all aspects of our lives. They are made for a vast variety of reasons ranging from the control of an industrial process through protection of our health or the environment to enforcement of a law or regulation. In all of these applications one aspect of all measurements is paramount: they need to be **reliable**. Furthermore, their reliability must be readily and widely accepted by those who use measurement data: the measurements need to be **credible**. This can be achieved through a combination of sound measurement science and the application of a quality system.

What do we mean by 'quality' and 'quality system'? **Quality** is often taken as synonymous with excellence and certainly scientific excellence is an important element of the quality of measurements. A more pragmatic, and useful, concept is one of 'fitness for purpose' or 'satisfying the customer's need'. Using this approach quality is seen to require a trade-off between excellence, cost and time. This requirement will be familiar to almost all those concerned with making measurements. What is not always familiar is the need to agree with the customer the requirement, or specification, for a specific measurement and the combination of the contributing factors which will best achieve it. Having agreed a specification it is essential to meet it, not just once but for **all** of the measurements to be made. It is also important that those who use the data, either now or in the future, are aware of any inherent limitations imposed by the specification. The **quality system** describes the activities aimed at achieving these goals. This chapter gives a brief overview of quality systems and how they are implemented. It is important to reiterate, however, that reliable measurements which are fit for their purpose depend on **both** an effective quality system and good measurement science. This is true regardless of whether the measurements are made for a mundane application or at the highest metrological level.

A quality system does not come for free. Most organisations will need to undertake substantial extra work to implement an appropriate system and will also incur additional ongoing costs. It is frequently estimated that overall operational costs of a typical measurement laboratory may increase by 10–20% on introduction of a quality system. The costs fall into three main areas: activities necessary to prevent unreliable data from being generated; activities required to monitor the quality of the data; and the costs of repeating measurements found to be unreliable. The goal of the quality system should be to prevent errors rather than to find them. Hence the third cost should, ideally, be minimal once the system is in place. Indeed, the reduction of correction costs is widely recognised as a benefit which can be offset against the cost of the system. Most other benefits

are as important but less tangible. They include the costs of the faulty products or wrong decisions which may be a consequence of unreliable data. Others relate to the ability of an organisation to win or retain customers, its image or credibility, and staff morale.

A quality system is not a traditional feature of most measurement laboratories or facilities. Also, it is not something which can be left to the individual measurement scientist. Implementing a quality system requires management commitment to develop and resource a quality assurance programme. This embraces a variety of activities designed to ensure the product is reliable in the first place, specific quality control measures to monitor product quality on a routine basis, and activities designed to ensure that the rest of the quality assurance programme is being properly implemented. Some of the most important elements of a quality assurance programme are described in the remainder of this chapter. One aspect not described explicitly is the quality manual and related documentation which is a major feature of all quality systems. There is no single standard format for such material, but detailed examples can be found in appropriate textbooks or the guidance notes produced by external quality assessment schemes. Regardless of the style adopted it is advisable to keep documentation to the minimum necessary to achieve its purpose. Good documentation is a key feature of an effective quality system and its preparation frequently appears to be the major burden of implementing a new quality assurance programme. It cannot be emphasised too strongly, however, that the existence of the documentation, no matter how extensive, does not guarantee reliable measurements. This can only be achieved by establishing an effective quality assurance programme and ensuring that it is applied carefully and sensibly on a daily basis.

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