

Standards on Commissioning and Manufacturing Dental Appliances

Response from Nigel J Knott BDS LDS RCS (Eng.) RDT to the GDC Invitation to Comment on the Consultation Document

Excerpts from Pages 3 and 5 of GDC Consultation Document

“Our draft standards supplement the requirements of the MHRA and are intended to ensure that there are no gaps in patient protection in relation to the commissioning and manufacturing of dental appliances either in the UK or overseas.

We are keen to hear from dentists, CDTs, dental technicians and other GDC registrants, as well as professional associations, patients and patient groups who could all be affected by these Standards.

Registrants who make dental appliances

If you make a dental appliance, you must understand and comply with your legal responsibilities as “manufacturer” under the Medical Devices Directive. These are legal requirements rather than GDC rules and the GDC expects you to fulfil these responsibilities and will hold you accountable for doing so. The Medical Devices Directive requirements include, amongst other items:

- 1. registration of the manufacturer with the Medicines and Healthcare Products Regulatory Agency (MHRA)*
- 2. use of CE marked materials*
- 3. defined manufacturing process*
- 4. calibration and maintenance of equipment*
- 5. cleanliness and infection control*
- 6. packaging and labelling*

About the Author

The author of this document has spent the last thirty years developing methods whereby dental prostheses can be manufactured to within clearly defined error budgets. He set up his own private practice in 1981 and a commercial dental laboratory three years later. He researched the manufacturing of complete dentures and developed a unique method of manufacturing precisely fitting clinically unbreakable resin dentures known as the “Accord Denture System”. His work into the behaviour of

impression and dental laboratory replication techniques used advanced metrology methods that enabled him to validate and certificate the unique manufacturing process with patient warranties. These methods were the precursor of the advanced analytical technology embraced within computerised measuring systems used today in conjunction with contact scanning procedures. He has represented his profession on the BDA Representative Board and the Dental Laboratories Association on The British Standards Institution Dental Materials Committee (HCC51). He was a Dental Advisor to The Secretary of State for Health and Social Services Patrick (now Lord) Jenkin and introduced the concept of Dental Health Trusts that was recommended by Sir Kenneth Bloomfield in his Report (1992).He contributes regularly with articles published in the Dental Press.

Introduction

It is an appropriate time for the GDC to undertake a detailed appraisal of dental Standards. The registration of dental technicians and the widespread use of remote manufacturing facilities overseas will bring new challenges for the GDC that can only be addressed by introducing objective methods of assessment and audit based upon science.

It is the responsibility of the GDC to protect the best interests of patients and ensure that high quality education facilities are maintained for the training of all dental professionals. A well-established procedure for monitoring professional care is presently encapsulated within the GDC Standards for Dental Professionals set by the GDC Standards Committee.

It is no less important to ensure that the manufacturing of dental appliances is included in an overall GDC standardisation process. Whilst this specific task remains in the remit of the GDC itself, it cannot control every aspect and should make every effort to ensure that suitable arrangements are in place and manufacturing Standards established.

Registered dental technologists working in laboratories are part of the UK manufacturing industry. It is appropriate therefore to ensure that suitable manufacturing Standards exist that recognise the need to measure the quality and effectiveness of the manufactured products themselves – dental prostheses or dental appliances. The British Standards Institution is the appropriate body to carry out this specialised task and the GDC should make every effort to add to and improve the BSI Dental Standards already in existence and delegate responsibility accordingly.

As we shall read later there is a grave danger of creating confusion instead of certainty in this complex area of technology with too many cooks being involved. The use of italics to describe Registrants who make dental appliances as

“manufacturers” is in itself confusing. Why are the italics used in connection with a clearly defined manufacturing responsibility?

Manufacturing Standards are long overdue but these fall outside the remit and capabilities of the GDC. Responsibility should rest within the dental laboratory industry itself together with BSI.

The Manufacturing of Dental Appliances

The application of specialised Computer Aided Design and Computer Assisted Manufacturing (CAD/CAM) techniques, accompanied by electronic communication technology brings opportunities that will revolutionise the manufacturing of dental appliances. The task of identifying responsibilities (accountability) in the dental appliance manufacturing chain and measuring production methods and process controls against suitable Standards is an imperative. These responsibilities must be clearly defined as part of a recognised audit trail in order to remedy shortcomings and failures. It is not acceptable to make a dentist or a technician responsible for areas of production that are still not standardised, benchmarked or little understood. The new GDC proposals are fraught with danger.

The GDC must address therefore the immediate problem created by the lack of any suitable Product Standards that must apply to the manufacturing of dental appliances. Without an ability to audit and trace every stage from commissioning to supply, success or failure can never be properly measured nor can responsibilities be apportioned. The “accountability principle” mentioned in the Consultation Process can never be fulfilled without clearly defined Product Standards. Indeed how can a Registered Dental Technologist presently be expected to monitor and understand the manufacturing process of every prosthetic appliance made in China or India for example? The China /India/UK/EU production arguments would be quickly dispelled with effective Product Standards being in place. The use of CE Marks in their present state is totally inadequate and it is not difficult to foresee situations in which the existence of traces of lead in toys made in China become trivial events when compared with the potential hazards of dental prostheses in far off places!

We cannot ignore any longer the ability of CAD/CAM technology to control the manufacturing process and deliver products that are supplied with certificates of conformity, accuracy and safety. In the continual drive to reach the pinnacles of clinical and technical excellence we need benchmarks that will measure precisely, clinical and technical performance. Whilst the clinical aspects may be more difficult to define and measure there can be no excuse for delivering laboratory products that fail to measure up to approved Standards - dental appliances that do not fit!

The Victorian scientist Lord Kelvin made the following statement that still holds true today “When you can measure what you are talking about and express it in numbers you know something about it, but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind”. Most dental prostheses measured by Lord Kelvin’s yardstick would be classified today as being unsatisfactory.

If we go even further back in our history books to AD1215 we will find at Chapter XLI of the Magna Charta “There shall be one measure of wine throughout our kingdom, and one measure of ale, and one measure of corn, viz. the London-Quarter”. Even in those days people objected to being short changed. How could we ever measure success or failure on the sports field without numbers to convey the results of competition? How can we measure the worth of any manufactured product without performance figures? Standards expressed in numbers we can recognise and understand help us to understand and make better informed choices. As consumers we are able to do so more often than not with manufacturers competing and seeking to gain market share with the best quality products and brands. Some sectors of the market are much better served than others and dentistry is particularly poorly catered for in terms of measuring product performance and providing certification. How can a patient decide whether a set of dentures priced at £600 is worth twice the value of a set at £300? Why is a precision fit ceramic crown more expensive than a non precious metal crown? What is the difference between a crown made under the terms and conditions of the NHS and a more expensive private counterpart? These and many more questions have to be answered honestly and transparently. However in the absence of some Standard of Measurement it is impossible for a dentist to price products equitably and for patients to make any value judgements upon the worth of any dental product or service they purchase from a professional supplier.

The Principal of Accountability

Within the field of science itself we can introduce methods of accountability based upon certainty. The GDC proposals arbitrarily apportion personal responsibilities and it is no good being able to identify exactly where the buck stops if the regulations do not lay down in plain English what the rules of the game are. In this particular example the design and composition of the buck itself and the bats used to strike it are essential ingredients that are missing. Whilst the audit trail is an important mechanism in any accountability process control we have to understand at each stage of the manufacturing process what is going on. Our dental process actually begins in the surgery at the design stage that must involve both the clinician and the technician in order to agree a treatment plan and estimate of costs. It is not acceptable that the commissioner, facilitator and clinical provider remains in isolation from the manufacturing process itself. A vast number of prosthetic appliances fail simply because the designs are flawed and the impressions themselves used to manufacture a clinical replica are inaccurate. If the dentist is to remain in charge of the complete dental process then we all need to understand in minute detail what this process is!

The Use of Standards in Everyday Life

Nearly everything we use in the modern world is the subject of a Standard and life would be much more difficult and hazardous without. Our clothes are made to a particular size, batteries are sold on size and capacity, cars are sold with

performance specifications and our wines and spirits are no longer sold by the London Quarter but in litres and centilitres. Even the paper we use in correspondence meets a particular size and quality Standard. Laws ensure the products we buy do what they say on the tin and dentistry should be no different. In dentistry we could be accused of double standards or more correctly a lack of Standards. Where else would we be allowed to use the term “fit” to describe the manner in which a dental prosthesis “approximates” to the tooth surfaces or soft tissues of the mouth – in other words it “fits where it hits”? As we know only too well the term “fit” presently covers any dental restoration (fixed or removable) that is placed in the mouth whether by hook or by crook and in marked contrast to one that has been properly engineered using CAD/CAM technology! **This situation is unacceptable as it destroys the value of pricing mechanisms together with patient trust and confidence.**

A dental laboratory owner will often claim success because all of the work sent out to dental surgeries is “fitted” and there are rarely any remakes or returns. In dentistry the expression “if the cap fits wear it” takes on a wry significance. But of course the question concerning the quality of the clinical fit of items placed in such a sensitive part of the body as the mouth is so crucially important. It should hardly be necessary to spell out the implications of a crown or bridge that has been crudely “adjusted” at the chair-side before it is permanently cemented in place. All of us are aware how much the quality of a crown, a denture or a bridge can vary but how can we measure or validate and certify the various properties in objective scientific terms? One thing is certain – if we ourselves as dentists are uncertain then our patients will be even more so. Without any measuring tools the task of the GDC in setting draft standards (Standards?) describing the responsibilities of dentists, dental technicians and clinical dental technicians for the safety and quality of dental appliances is a hopeless one.

In everyday life we are only too well aware of the consequences of badly fitting clothes or perhaps blisters and sores as a result of ill-fitting shoes. As consumers we are also equipped to remedy the situation with well - recognised consumer protection measures. Whilst far too many patients are familiar almost immediately with the consequences of ill-fitting dentures or orthodontic appliances, those with ill-fitting crowns and bridges may have to wait a little longer for the discomforting symptoms of an abscess or a fracture to occur! Seeking remedial care and possible redress can be a patient nightmare and the consequences of manufacturing error often put down to patient carelessness.

Computerisation

The use of CAD/CAM technology today is widespread and benefits us all in our everyday lives in a variety of ways. It ensures the cylinders in car engines fit within clearly defined tolerances with a spectacular increase in performance when compared with engines made in bygone days when skill and craft were at a premium. And yet in dentistry we are still using the term “fit” as a measure of success in absolute terms in the absence of any benchmark or relative measure. In engineering parlance we are failing to measure the performance of our dental products and publish the results within clearly expressed boundaries of

uncertainty. Where the soft tissues are concerned exact measurements are so much more difficult to assess and comfort is perhaps the most important property in any definition of fit. So for example a denture or a mouth guard might prove to be extremely comfortable and fit like a glove.

Today we are able to utilise CAD/CAM controlled systems to govern the delivery of engineered dental solutions and be much more objective and certain in our analysis of the surfaces of a crown, a bridge or a denture when fitted to hard or soft tissues in the mouth.

A poorly fitting crown or bridge can rapidly loosen and lead to a dental abscess or catastrophic fracture. Any assessment of fit therefore must not be restricted to a subjective visual analysis at the clinical assessment stage but also must include a detailed metrology analysis that takes into account the cementation process and the suitability of the chosen materials. Without any benchmarks or technical specifications how can a dentist be certain that all the information is available to ensure the right material ingredients and manufacturing processes can be chosen and approved with confidence? How can we believe all of the glossy advertising and expensive marketing initiatives from so many different dental material and equipment manufacturers supporting a plethora of brands all claiming to give the best results? Are all dental porcelains and acrylics the same? Are all CAD/CAM systems the same? Are all impression materials the same? No they are not.

Where the use of CAD/CAM technology is concerned it is particularly important for a standardised scientific analysis of the computerised processes themselves to be introduced. Indeed "*The calibration and maintenance of equipment*" goes much further than the authors of the GDC Consultation probably ever realised! For example, where are the Standards used for the calibration of scanners employing laser or structured light technology as opposed to contact scanners regulated by BSI/EN/ISO 10360 Pt IV?

It is of particular concern to read so many supposedly authoritative clinical articles that include measurements in microns and personally subjective performance judgements sowing the seeds in the minds of readers that fantastic accuracy and precision have been achieved – all in the absence of any Standard to prove the veracity of the claim! It is one thing using feet and inches or metres and millimetres as most people have a reasonable chance of assessing the truth of the matter personally but quite another when specialised equipment is needed to prove the point in microns or even nanometres.

Probably the greatest damage can be caused by a failure to regulate the publication of false or misleading claims in dental marketing/advertising literature and professional magazines/journals where the audit procedure is governed more frequently by commercial benefits than by science. For example a Company claiming that an impression material is "ultra accurate" in the absence of any scientific proof should be called to account. The actual term itself is complete nonsense but is clearly designed to sell more products and probably does so very successfully.

As the use of dental CAD/CAM systems increases so does the need to monitor and evaluate the technology itself in the light of performance Standards to assist

dental professionals and patients alike in making properly informed choices. All of us at some stage in our professional careers have suffered as a result of failed materials and faulty technology used in good faith that should never have been placed in the dental market in the first place. "Caveat Emptor" can never be properly exercised in such a highly specialised market place as dentistry where Standards are insufficiently well developed and monitored to give everyone the necessary information and protection for fully informed choices and comparisons to be made.

What is a Standard?

A standard may be defined as a document for common and repeated application that provides rules, guidelines or characteristic features of activities or the results of these activities. The document has been drawn up by consensus and adopted by a recognised body such as BSI with the objective of achieving optimal order in a given context.

A benchmark is a permanent reference point that can be verified and is often used in business to set new levels of excellence in developing state of the art products for commercial advantage.

A good scientist has a challenging and enquiring mind. Erroneous assumptions, some of which are deeply entrenched even into the teaching schedules of dental undergraduates, must be exposed, questioned and corrected. Some Dental Standards and manufacturing controls (BS/EN/ISO and EC Medical Devices) are woefully inadequate and are largely responsible for a sense of false security in the belief they will guard against failure. Dental Material Standards tend to be set at unacceptably low levels in the absence of stated clinical and technical process objectives. But the most significant deficiency is the failure to adopt Standards that will identify and remove the uncertainty of measurement (Metrology). Far too much in dentistry is left to guesswork. Only by encouraging constant objective improvement can we benefit from the efforts of those who seek to push back the dental boundaries all too frequently associated with mediocrity.

The existing Dental Standards tend to set an average value in recognition of a bare minimum and fail to provide for state of the art benchmarks or any equivalent of a Kitemark®. In dentistry, perhaps the time has come to introduce Bite Marks or Dental Metrology Marks for products that are best in class!

Dental Standards and Quality Control

There are presently 156 Standards set by the Committee responsible for dental matters (ISO/TC 106) and there are for example 20 Standards used in the production and placement of a porcelain jacket crown. The European Standards Committee CEN/TC55 has adopted 123 as EN ISO Dental Standards. The increased use of computers is responsible for the development of a revised EN ISO-3950:1997 Standard in order to regularise the method used for the designation of teeth first introduced by the FDI nearly 25 years ago. This revision will be adopted by most of the 800,000 dentists in practice worldwide and will bring much needed familiarity with a uniform language for tooth recognition.

None of the existing Standards will bring us any nearer to measuring the fit

or performance of a fixed or removable dental prosthesis. These important properties could be incorporated as process controls within the scope of Standards BS EN ISO 13485; BS EN ISO 14971.

The physical separation of clinical operations from the technical support services of the dental laboratory frequently leads to sources of error that can be eliminated with the introduction of computer-controlled disciplines. What used to be separated into distinct clinical and laboratory stages should now become part of a seamless production process. In addition properly standardised material ingredients and process controls can ensure the delivery of right first time every time results. The use of advanced software programmes lends itself to becoming an integral part of any audit procedure. Computer Integrated Manufacturing (CIM) systems must be established to weld together the complex ingredients used in the manufacturing process. The setting of benchmark Standards and the use of these Standards form a crucial part of controlling the manufacturing process. An intimate knowledge of this specialised standardisation process should be a mandatory part of CPD and all undergraduate education and training programmes.

Our immediate task is to identify and remove as many variables as possible in order to bring consistency and certainty to everything we do in dentistry.

Remakes are direct costs on bottom line profit, and clinical failures bring the additional risks of loss of patient confidence, goodwill and even litigation. The use of advanced technology brings economy of scale and deskilling – two important ingredients in the constant struggle to bring down and control costs.

End-to-End Process Control

Whilst each BS EN ISO Standard may be fine in isolation we are faced in dentistry with a most complex chain of events where a rupture of one or more of the many delicate links can result in disaster. This chain of events, or process, needs to be codified and condensed into a recognisable production method or process control. Only then can we understand and measure in detail what is happening from the beginning to the end of any manufacturing procedure.

Rationalisation and integration on a scientific basis raises the issue of the various Standards that we are likely to encounter in business today and how we should apply them to our highly specialised dental tasks. The relevant Standards we need to consider are:-

- Terminology Standards – descriptions and language
- Management Standards – for example ISO 9000
- Material Standards – specific requirements for material composition
- Product Standards – design and marking requirements, process control, warranty and certification
- Testing Standards – compliance requirements and measurement
- Quality Standards – for Medical Devices BSI/EN/ISO 13485 & 14971
- Performance Standards – fitness for purpose and durability
- Advertising Standards – product description and veracity of claims

Strong process links supported with robust dental science are not sufficient on their own – the imprint of the art and craft of experienced dental professionals is still needed to complete any successful dental recipe. For example a need to recognise and understand at the design stage the impact of an unusual occlusion placing a stress premium on using porcelain in a crown that could result in fracture. Will any impression material give the same results when coupled with any model material? What is dental CAD/CAM and how is it to be employed? Why is the use of metrology so important?

Only a systematic approach can ensure every link is designed and welded into a robust manufacturing chain. That is not to say everything can be set in a tablet of stone, far from it, science is always in a dynamic state and ready to respond with new discovery. Science must form the foundations of evidence based dentistry and numbers used to measure success or failure in just the same way that we judge the performance of a vehicle in terms of petrol consumption or in human terms the speed athletes can run or the distance they can jump.

Standardising Dental Process

The extraordinary transformation initiated by the introduction of new technology and computerised processing methods demands some form of Dental Standardisation. Dental CAD/CAM technology must be considered in a generic light and the application of Standards familiar in other branches of industry need to be adapted and implemented accordingly. Perhaps the time is right to integrate dental technology into the field of bioengineering in order to benefit from many of the engineering Standards used on a daily basis globally. It is not only the patient that needs more information as a consumer but also the professionals themselves who attempt to make decisions they believe are in the best interests of their patients with the products they make and the services they provide – presently there is far too much smoke and too many mirrors to obscure the vision of all concerned!

So what should Dental Industry Standards look like in order to be relevant and useful? Standards should be considered a valuable protection and not a threat - a mechanism we can use to benefit our own welfare and the welfare of our patients also.

A brief outline of established Standards is appropriate at this juncture as any Standardised dental process will need to incorporate the following essentials

- A. **Terminology** – the language we use can sometimes be confusing when it means something different to other people working outside our specialised field. For example we tend to use the word “die” in conjunction with obtaining a replica of an impression in a way that is not familiar to an engineer - master model (or clinical replica if appropriate) would be a better term to use. The words “accurate”, “precise”, “replica” and even “ultra accurate” are carelessly inappropriate unless they can be validated by science in engineering terms. Is it a replica? How precisely can we measure the clinical fit? Indeed these terms could be interpreted as calculated to mislead if appearing in a commercial advertisement without any scientific evidence. An engineering company in the UK would

- inevitably be the subject of a complaint to the Advertising Standards Authority if they were unable to substantiate their claims. An accurate dental impression in engineering terms means a precise replica of the clinical geometry. How many manufacturers of impression materials can demonstrate this claim in scientific terms or better still what do they mean by “perfect impressions” in isolation of the clinical procedure itself?
- B. **Management and Reporting** – ISO 9000 is a familiar and respected business management Standard that ensures consistent and reliable systems of administration can deliver business efficiency. However this may not be enough and a reporting mechanism designed to introduce continuous improvement (again the aerospace industry sets the benchmark here) would be beneficial. The Medical Devices Directive and the Yellow Card Pharmaceuticals reporting mechanisms only address product failures after the event that may then require market intervention as a matter of urgency. But by this stage it may be too late and neither mechanism effectively addresses the quality improvement issue in advance. Where is the Standard that actually defines “fitness for purpose”? Just because a particular product is not fit for purpose, does not necessarily mean that all others are. We have to move on from the end of term School Report that is satisfactory to one which can measure success or failure.
- C. **Material Standards** – metrology research indicates that several different dental materials presently in the market place are unsuitable and not fit for purpose - despite the fact they comply with BS EN ISO Standards. For example the Standards that relate to impression materials (BS EN ISO 4823:2001 and the materials used to replicate dental impressions (BSI EN ISO 6873:2000) are woefully inadequate. The birth of every dental appliance begins at the vitally important impression stage. We can demonstrate that a very high percentage of dental impressions and master models will fail basic CAD testing methods introduced to identify a maximum error budget set within a 100 micron limit. Indeed the two dimensional BS/ISO impression material tests allow errors in excess of 0.5 mms! It is unacceptable that dentists should continue to supply impressions to dental technicians for the manufacture of properly fitting prostheses in the absence of any metrology analysis. The relevant Standards require urgent review.
- D. **Product Standard** – where can we find a set of definitions that describe each and every prosthetic appliance that is manufactured in a dental laboratory? Without a product definition we are unable to set any meaningful Standard and everything we do is of doubtful value. By clearly defining a crown, a bridge, a coping or a removable denture for example we can set the appropriate minimum benchmark Standards and methods of compliance.
- E. **Testing Standards** – we have already drawn attention to the key role of metrology and the actual technology employed in the measurement process and the validity of the results. Toxicology is another controversial

- issue and in particular the use of non precious metals in dental prostheses.
- F. **Quality Standards** – we are in grave danger of having too many cooks spoiling the broth in the absence of any proper glue holding everything together. It is the existence of the MHRA, BSI and now the GDC that will create massive confusion. Quality frameworks already exist within the parameters set by BSI/EN/ISO 13485 & 14971 and as we have identified already, without a measurement for quality we cannot ever exercise a value judgement where cost is concerned.
 - G. **Performance Standards** – this is perhaps the most important property of all and the necessary proof that quality matters most. How long has the prosthesis been designed to last? Does it fit properly? Is it safe (biocompatible)? These are perhaps the most important questions that a patient will expect to be addressed and in the absence of any benchmarks their questions are impossible to answer truthfully.
 - H. **Advertising Standards** –the General Dental Council (GDC) regulates registered dentists and other dental professionals, but there are no similar arrangements in place that apply to those working in the dental trade who make a crucial contribution to the manufacturing process. Advertising Standards in particular must be applied fairly and equitably to all those associated with the manufacturing chain of dental prostheses.

A Standard of Fit?

An intensive study of the literature suggests that the marginal space left by a dental crown not exceeding 100 microns is the optimum acceptable. The existing highly subjective “measure” of fit is based upon the fact that a new dental explorer (probe) will often exceed 90 microns (the approximate diameter of a human hair) and smaller spaces cannot be identified. A recent article (Journal of Prosthetic Dentistry 2005 93:138-142) reports that marginal errors of less than 124 microns cannot be detected with a dental explorer. Traditionally of course we have used a dental explorer to check upon the sub-gingival margins of a crown or bridge before cementation - any defects however are frequently hidden from view beneath the gingival margins. We have a considerable amount of evidence to prove to us the shortcomings of this and other traditional methods of assessing the marginal “fit”. With CAD/CAM technology we can be certain of our marginal fit when it is supported with a certificate of conformity and all the guesswork becomes a thing of the past. Not only can we validate today the accuracy of an impression and the master model cast from it but also we are able to measure the fitting surface of a dental prosthesis and compare the geometry of the two to ensure they are precisely matched. As a function of fit, the internal surface finish will be an important consideration as will the design of the cement space. In engineering the surface finish and the effect this has on the function of the component is taken very seriously and there are many instruments for measuring surface finish in addition to the Standard measurement parameters (against 5 different BS EN ISO Standards). Component surface finishes in dentistry should

also relate to the surface roughness of the prepared teeth and how they impact upon the choice and composition of the adhesive cement or resin together with the particle size of any filler. Where a zirconia coping is concerned the surface finish is important for two reasons – the first to ensure optimum porcelain bonding and the second to ensure permanent retention on the prepared tooth. Needless to say the practice of adjusting the surfaces of engineered components with a hand held dental turbine is not based upon best practice! In dentistry, “fit” cannot continue to be used in the absolute sense and we need to ensure any reference in the future is associated with clearly stated Standards.

Perhaps the time has come to plagiarise the Standards used to regulate electrical products that have to be sealed against the ingress of dust and/or moisture. For example BS EN 60529 sets degrees of protection that enclosures have to offer against microscopic particle or liquid penetration in a variety of circumstances. The immersion of an electrical appliance in a pressurised fluid environment demands the highest fluid Ingress Protection (IP) Rating whilst a light bulb is the subject of a much less demanding IP Rating. In N America another classification adopted by NEMA (National Electrical Manufacturers Association) Standard, goes even further by including tests against mechanical damage (from accidental collision), corrosion, rust and even ice formation protection. There would seem to be a correlation here as very often we are looking in dentistry to permanently seal and protect the sensitive tissues of a vital tooth from the aggressive influences found in a very demanding environment – the mouth. The permanent marginal seal of a fixed dental prosthesis therefore is crucial and a dental ingress protection rating (DIPR) would be highly appropriate where a NEMA type Standard would recognise antibacterial properties as well.

Ethical requirements

In some respects the rather outdated but necessary Ethical Standards set by the regulatory authority, the GDC, have tended to act as a brake upon the recognition and promotion of clinical and technical excellence. It is not too long ago that the advertising and marketing of dental practices and professional services were virtually proscribed. Practitioners who had achieved the highest honours in their competitive University Finals were not allowed to register the fact with the GDC or advertise it to the public on their practice letterheads. Even today any claim a dental practitioner makes in respect of superior personal skills, craftsmanship or experience will be met with formal disciplinary proceedings regardless of the truth of the claim! Ample evidence is gathering in support of the view that self-regulation may not be working too well in dentistry and could be responsible for holding back much needed market reform. Patient best interests cannot be served in an atmosphere of uncertainty and information barriers – “trust me I am a dentist will no longer wash”!

Now that science is in the ascendant, life at the premium end of the market may become a little easier for professionals to promote products in a way that patients can easily recognise and be able to compare their value more easily. The profession has been slow to champion any product standards that use scientific benchmarks in the manufacturing process. Being associated with state of the art

products and benchmarked process controls will by implication be associated with higher standards of professional care. Patients now expect an expensive dental prosthesis to be supplied with a warranty as in any other area of consumerism. In dentistry, new brand values will be able to provide an important protection for all concerned and competition is a market advantage that should be enjoyed by dentist, their patients and consumers alike. These brand values should be able to utilise benchmark Standards as comparisons of worth. Will the dental resin and bonding system prove suitable for the permanent placement of a crown or bridge? Is the crown properly designed and unlikely to fracture? Has the vitality of the tooth been preserved and protected? These are just a few more of the questions that have to be addressed.

In every walk of life a consumer expects the products they buy to carry some form of warranty and instructions for use – a dental crown, a bridge, a mouth guard or a complete set of dentures should be no different. With the application of advanced analytical tools we will be able to combine experience and knowledge to develop superb materials and state of the art processes supported by performance warranties. Caveat emptor will then carry a new meaning in dentistry and give patients the freedom of choice they need in a pretty confused market place where meaningful Standards are sadly lacking.

Summary

- 1) The GDC is responsible for professional and educational standards and is not the appropriate body to set or regulate manufacturing standards for dental appliances
- 2) Standards relating to the commissioning and manufacturing of dental appliances should be in the domain of the British Standards Institution (BSI)
- 3) BSI should be given the lead responsibility in the setting of all dental Standards where materials, processes and clinical products are concerned
- 4) Product Standards in respect of the manufacturing of dental prostheses should be introduced as a matter of urgency
- 5) The use of CAD/CAM technology and electronic communications are important new disciplines that need to be properly integrated within dental manufacturing systems (CIM) and made the subject of proper Standards
- 6) The GDC must recognise the need to revise undergraduate training schedules and post graduate teaching programmes (CPD) to include the disciplines of Computer Assisted Design and Manufacturing (CAD/CAM) and Metrology
- 7) GDC Registration must include properly funded education and training programmes that recognise the importance of integrating dental technology within the clinical curriculum
- 8) Patient care should include the certification of dental appliances manufactured within standardised process controls and regulated by Product Standards set by BSI

Nigel Knott
20 June 2008