

# QUALITY PRODUCTS AND QUALITY FOR PATIENTS -- ISO9002 FOR MANUFACTURE AND CLINICAL SERVICE.

S.E. Crook, I.D. Swain, P.N. Taylor, S. Finn.

Department of Medical Physics and Biomedical Engineering,

Salisbury District Hospital, Salisbury, UK

## SUMMARY

In 1998 it became illegal to supply a Medical Device within the EC without a CE mark. The purpose of the mark was to harmonise the various safety requirements of the Member States which were otherwise becoming a barrier to trade. Companies or Institutes manufacturing medical devices now need to show documented compliance with the Medical Devices Directive (MDD) /1/. It was no longer sufficient to have engineers taking professional responsibility for their work. To demonstrate consistency and good quality the MDD required that a Quality Management System (QMS) be in place as part of the manufacture of medical devices.

The Odstock Dropped Foot Stimulator (ODFS) is a body worn, battery operated stimulator which was being increasingly widely used across the UK. Review of the MDD showed that an externally verified QMS would be required if we wished to continue to supply the ODFS outside of our Institution. Since the clinical service was increasing as well, the decision was made to include both the manufacture and patient treatment in our QMS assessment. The route to this successful implementation is described along with the advantages and drawbacks encountered.

## STATE OF THE ART

At the time of the June 1998 deadline for CE marking commercial companies had moved to comply with the MDD for products they wished to continue to sell. Most hospital departments viewed the work involved as excessive but the ODFS was a successful product and in Salisbury preparations were started over a year before the deadline.

In the UK the National Health Service (NHS) was in a period where internal (between hospital) competition was encouraged. It was considered that an externally recognised validation of the quality of our patient treatment would give us an advantage in this environment. It is important to note that external assessment is only concerned with how well we deal with patients or how consistently we can make stimulators. It is not an endorsement of the effectiveness of our treatment.

## METHOD

### Choosing the Assessment route through the MDD

The first step is to confirm that your product is a Medical Device within the definition of the MDD. The ODFS is a Medical Device because its purpose is "alleviation of or compensation for an injury or handicap" (MDD, Art 1, para 2(a)). By reference to Annex IX of the MDD a muscle stimulator that uses skin surface electrodes falls into Class IIa. This was confirmed with the Medical Devices Agency which is the UK Competent Authority overseeing implementation of the MDD.

Once the class of your device has been established it is necessary to choose a Conformity Assessment procedure (Art. 11, MDD). For the Department in Salisbury it was decided to comply with Annex V (Production quality assurance) which would require a QMS verified by a Notified Body. A Notified

Body is simply a company that has been approved by the Competent Authority to award a certificate showing compliance with the MDD. The MDD does not specify how a QMS should be designed, only that it should be externally verified by a Notified Body. In practice this means that the international standard ISO9000:1994 /2/ should be used since Notified Bodies are familiar with systems based on this document so accreditation would be more straight forward.

(N.B The 1994 edition of ISO9000 is being replaced by ISO9000:2000 with a phased assessment program for existing certificate holders.)

### Starting up a Quality System

Upon reading the ISO9000:1994 set of documents a decision had to be made as to which individual standard would be used. Since we were not offering a design service for our customers we would not generate appropriate records for ISO9001 which included design. ISO9002 covers production from start to finish of an existing design and ISO9003 covers testing of a finished product. Since we would be developing our own products we wanted a system that covered their manufacture so ISO9002:1994 was chosen. In the case of medical devices a supplemental standard, BS EN 46002:1994 /3/, is also required and this was included when the quality system was being developed.

### Stimulator Manufacture

This activity was judged to be a priority since non-achievement of the ability to CE mark would prevent us supplying stimulators outside of our hospital. A Quality Manager was designated to oversee the introduction and running of the system. In order to reduce the time taken to compile the procedures required by ISO9002 a management consultant was employed. In consultation with the staff doing a particular job he was able to look at the way we were working and write a procedure that would satisfy the requirements of the standard. In almost every area the requirement was for traceable records to be made showing that a specific check or activity had been carried out. Therefore record books had to be modified or introduced to hold these records.

In order to affix a CE mark a Technical File for each medical device needs to be kept. This will contain manufacturing and design drawings, risk assessments, product compliance with other standards, instruction manuals and so on. Approximately half of the required documents were available before the Technical File was put together for the ODFS. The remainder had to be generated specifically.

An external company was used to verify compliance with EMC standards and the pass certificate was inserted in the Technical File. Since this is a costly process some pre-testing was done at a local EMC facility and slight modifications made in order to guarantee compliance. For compliance with the applicable electrical safety standard (BS EN 60601-1 /4/) a checklist was completed by the designer and signed off before insertion into the Technical File.

Once the procedures had been in use for several months an audit of the QMS was carried out to determine how well it was working.. The audit is itself a requirement of ISO9002 and any shortcomings need to be addressed by staff training or modification of the procedures. Staff not involved in the area being audited should be used to carry out the audit. This prevents assumptions being made about the activity being carried out and ensures the auditor follows the procedures and records applicable for that area.

At audit or during normal operation a failure in the QMS needs to receive attention. Such failures are typically called non-conformances and they can arise from a manufactured item not reaching the required specification or a delivery containing the wrong goods etc. Non conformances are logged on

a form together with the measures taken to correct any problems. These forms are then reviewed at management meetings where measures to prevent any recurrence are discussed and implemented. When an external assessor reviews the operation of the QMS these non-conformances and the actions taken will be examined so minutes should be kept in sufficient detail to permit this.

#### A Quality System for Patient Treatment

Our method of treating patients with the ODFS had been carefully worked out over several years /5/ with input from engineers and physiotherapists. Several forms were in use in the clinic to collect data about patient performance and equipment settings. This data was then used to demonstrate the effectiveness of the device and highlight any perceived problems. The results were published in the scientific press.

Introduction of the QMS only required slight modification of these clinic forms to record the person completing them, some equipment details and confirmation that the patient had received instructions. A procedure was written to cover the operation of the clinic which then specified the use of the new forms.

As patient numbers increased the administration for the appointments and funding also required a procedure to be written. The ISO9002:1994 standard uses language that is very focused on 'the customer' and the contract between the customer and supplier. Whilst the obvious conclusion would be that the patient was our customer, in practice our contract is with the doctor or health authority. Contract review is a central ISO9000 requirement so it is these people that need to be informed about our service before we can agree to see their patient(s). This required information on the treatment to be sent to the referring doctors before their patients could be seen.

#### The Assessment

The Notified Body selected to carry out the external assessment of our QMS was the British Standards Institute (BSI). A Client Manager was assigned to us on the basis of our operation, i.e. electrical engineering for medical device production. A pre-assessment visit was made to ensure that the system we had was ready for assessment both on ISO9002 and the MDD. Since our Client Manager felt that the patient treatment aspect of our work fell outside his expertise a second BSI Assessor was brought in to do this assessment at later date.

Assessment of the QMS for stimulator CE marking took two days initially and a number of shortcomings or non-conformances were discovered. However, these were not sufficiently serious to prevent granting of the EC Certificate and a Certificate showing compliance with ISO9002. A plan showing how these non-conformances would be rectified had to be submitted to the assessor and approved before the certificates were awarded. After six months an assessor for the patient treatment came to look at this aspect of our operation in addition to a follow up visit for the manufacture. Our patient treatment activities were then added to the ISO9002 certificate.

Assessments then take place at six monthly intervals to ensure the QMS is being maintained. In addition the assessor will wish to see how the QMS system is being used to improve quality by monitoring such activities as repair, customer complaints and other non-conformances.

### RESULTS AND DISCUSSION

#### Benefits

The major beneficial result of achieving the ISO9002 registration is that we can continue to make stimulators for supply outside our hospital. This extends the benefit of the treatment and generates

some income to continue development of the ODFS and other devices. We now supply to several countries in Europe. For this we need to translate the instruction manuals and other safety information (e.g. labelling)

Records that are kept as part of the QMS have improved the way we run the manufacture and especially the patient treatment. Any other devices we design can be brought into our system and CE marked. Similarly we can take on the role of manufacturer for products designed elsewhere and CE mark those.

### Drawbacks

There is some extra work to do and there was staff resistance to overcome. However, the day to day running of the QMS is very smooth and the kind of records we now keep should probably be kept by a responsible department in any case. When audits, reviews and assessments take place there is a high workload on the Quality Manager which should not be underestimated. In addition there are costs for the Notified Body amounting to £2500/year.

### Conclusions

Whenever some question arises as to the value of the QMS and the other documentation it is helpful to consider what would happen if a product we had manufactured were involved in a serious incident that harmed a patient. In a court room or other inquiry questions would be asked about the quality of our products. In such a case there is ample documentation to demonstrate that our products have been properly designed and made. This was probably not the case before the MDD requirements. There are also continuous benefits from the improvement in record keeping and the documentation of procedures.

## REFERENCES

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/4/ BS EN 60601-1:1990 Medical Electrical equipment Part 1 General requirements for safety 1997 BSI, London

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## AUTHORS ADDRESS

Dr. Steven Crook  
Department of Medical Physics  
Salisbury SP2 8BJ, UK

email: [s.crook@salisburyfes.com](mailto:s.crook@salisburyfes.com)  
[www.salisburyfes.com](http://www.salisburyfes.com)