

## **The use of ISO 9000 Registration by The Institute of Reconstructive Sciences in Medicine (iRSM)**

The Institute of Reconstructive Sciences in Medicine, located at the Misericordia Hospital in Edmonton, is a multidisciplinary unit that specializes in restoring the appearance and function of patients suffering from craniofacial deformities due to disease, trauma or birth defects. One method of restoration that iRSM uses is referred to as Osseointegration, a technique that involves the placement of titanium fixtures in bone that become anchors for prosthesis to replace eyes, ears and teeth

In January, 1998 COMPRU (which later became known as iRSM) became the first publicly funded health care delivery facility in Canada to become ISO 9000 registered. Until then, this system was typically applied to manufacturing and production settings. It was adopted by COMPRU as a tool to standardize and continuously improve care of their patients who received treatment for their deformities using osseointegration technology.

ISO 9000 is a system developed by the International Organization for Standardization. The ISO 9000 standard consists of 3 levels - 9001 (the most comprehensive) 9002 (shorter version of 9001 but without the design element) and 9003. Currently iRSM holds a 9002 standing. ISO 9000 is used as a tool to ensure a consistent level of quality in the delivery of a product and customer satisfaction.

The ISO 9000 Mantra is: Plan what you do, do what you plan and prove it. By using the ISO 9000 framework, iRSM can meticulously plot the patient's rehabilitation journey. The unit draws from a vast interdisciplinary team including (to name a few) surgeons, prosthodontists, audiologists, speech pathologists, surgical design specialists and nurses to plan, implement and document treatments. Research is also a priority in iRSM. The data collected from patient treatment and outcomes is shared globally.

In order to become ISO 9000 registered, COMPRU developed its own quality system which was then submitted to a comprehensive third party audit. Thereafter, the unit underwent annual maintenance audits to ensure continuous improvement in the delivery of patient care.

This process continues in iRSM today and the audits encompass the O.R and the nurses on the "osseo team". In fact, only "osseo" trained nurses are involved in osseointegration procedures in the O.R. at the Misericordia. The training program introduces incoming nurses to all departments and personnel involved in the osseointegration rehabilitation process. They receive ISO 9000 training. They then are trained in scrubbing, circulating and documentation by experienced team members

The ISO 9000 program also enables us to comprehensively track inventory - from determining requirements, to ordering and receiving and finally to implantation. It allows us to identify and report non conformities and develop solutions.

In summary, the ISO 9000 registration is used by iRSM as a management, clinical and research tool in order to realize its Mission Statement:

Commitment to consistently high quality osseointegration rehabilitative care for the patients through:

Conformance to treatment and follow-up care processes  
Continuous assessment of treatment outcomes  
Continuous improvement

Submitted by Kathleen Haring RN, CPN (C)

References:

(Caritas Health Group News Letter, Jan 28, 1998).

COMPRU registers an ISO9002 Quality System for Osseointegration (publication and date unknown)

Technologists: A Front Line Look at ISO 9000; Cathy Cardy MCIC,cCT;  
Canadian Chemical News, Oct 1993

Michele Gervais RN, Personal Communication