THE FLAGSHIP OF CUSTOM MAGNETICS
SINCE 1939

201 ENSIGN ROAD
BELLEVUE, IOWA 52031
PHONE: 630-628-9999 (Sales)
FACSIMILE: 630-628-9922

File # **FTB-019**	Title: **ISO 9001 Design Control**	
Author: **Steve Ensign BSEE**	Word Count: **421**	Date Submitted: Oct. 3, 16

The set of international quality system management standards known as ISO 9000 has been around for a long time. One of the key sections of the standard is Design Control. As the name suggests, Design Control requires every step in the design process to be documented, reviewed, and controlled.

Procedures start with the customer's specifications, called "design input" by ISO 9000. These must be reviewed before they can be processed. Each design project must include a "design plan", which details the anticipated steps to be taken in order to arrive at a compliant design, called "design output". The design plan, and any changes made to the plan, must be reviewed and documented.

Also required are documented procedures for "design verification", which is ISO 9000 terminology for making certain that the design output actually does satisfy the demands of the design input. Finally, the design enters the "design validation" phase, which is loosely defined as authorization to produce. For firms doing custom designing, this nearly always requires customer involvement. All aspects of design verification and design validation must be governed by documented procedures.

If the design is ever changed, procedures must exist to ascertain the impact of the changes in complying with the design input requirements, and whether re-verification and re-validation are necessary. The evaluation and implementation of the change must be reviewed and documented.

The point of all this, of course, is to ensure that customer requirements are always met, and that any customer changes and modifications to the specifications are reviewed, evaluated, communicated, controlled, and implemented mistake-free, every time.

In the past, manufacturing firms had the option of becoming registered to ISO 9001 which <u>includes</u> design control within the scope of the registration, or to ISO 9002 by <u>excluding</u> the design functions. This made it easy to spot those firms not having design functions under control to ISO 9000 standards. With the release of the year 2000 version of the ISO 9000 set of standards, this changes. ISO 9002 has been eliminated. Everyone will have to comply with the ISO 9001 requirements. Firms will no longer have the option of excluding design control. ISO 9002 registered firms must get their design functions up to standard, or they will lose their registration.

Ensign Corp never considered ISO 9002. Design control was an integral part of our ISO 9000 effort from the beginning. We are, and have always been, a design house. ISO 9002 would never do. We are proud of having achieved ISO 9001 registration, including design control, on our first attempt.