

- proof of tests performed on the equipment;
- proof that the product is not toxic;
- four copies of the instruction manual in Spanish;
- clinical information and case back-up showing the efficacy and non-deleterious effects of the equipment; and
- proof of approval by the normative body in the country of origin.

Once the equipment is approved, the *Secretaría de Salud* will provide a registration number. This registration number should appear on the import documentation.

PRIVATE HEALTH CARE SYSTEM

The Private Health Care System accepts the equipment registration and approval of the *Secretaría de Salud (SS)*, Secretariat of Health. A manufacturing company or the agent must then work with the individual hospital medical teams to convince them of the merits of the equipment. The medical teams subsequently request the specific equipment through the purchasing department. Establishing a presence with targeted hospitals is essential to entering this market. End-users will be inclined to select a piece of equipment with which they are familiar, even if the price is a little higher.

SPECIALIZED INSTITUTES

The *Institutos Especializados*, Specialized Institutes, operate very independently from the *Secretaría de Salud (SS)*, Secretariat of Health, with respect to designating and purchasing equipment. In order to convince the medical teams within the *Institutos*, companies need to make formal presentations to the appropriate team members. Depending on the complexity of the technology involved, a company should be prepared to pay the *Institutos* to conduct testing of the equipment and to carry out a clinical investigation. New equipment will be approved on this basis and once approved, it is eligible to be ordered.

STANDARDS

Product standards, *Normas Oficiales Mexicanas (NOMs)*, are an important consideration for companies exporting medical equipment to Mexico. Standards are established by the *Dirección General de Normas (DGN)*, Bureau of Standards, which falls within the purview of the *Secretaría de Comercio y Fomento Industrial (SECOFI)*, Secretariat of Commerce and Industrial Development. The *DGN* is the department, within *SECOFI*, which establishes the weight and measurement standards for the country. The metric system is used in Mexico and measurements are based on the International System of Units.

