



## **FREQUENTLY ASKED QUESTIONS**

### **FREESTANDING OR MEDICAL TECHNOLOGY**



**July 1, 2009**

#### **1. Is there a regulation for Freestanding or Mobile Technology?**

Yes. The regulation became effective May 28, 2004, the date of publishing in the *State Register*. The Freestanding or Mobile Technology Regulation 61-108 and an application for licensing are posted on the DHEC Health Licensing Website <http://www.scdhec.gov/health/licen/> and they are available in PDF Format for free downloading:

Regulation 61-108

<http://www.scdhec.net/health/hrreg.htm>

Application - Outpatient  
Care Activity or Service

<http://www.scdhec.net/health/licen/forms.htm>

Printed copies of the regulation are available upon request for a charge of \$10. An application for licensing Freestanding or Mobile Technology will also be included for those interested in pursuing licensing.

#### **2. Explain the requirements that must apply before medical equipment can be licensed as Freestanding or Mobile Technology.**

By definition, Freestanding or Mobile Technology is “medical equipment which is to be used for diagnosis or treatment and is owned or operated by a person, other than a health care facility (as defined in S.C. Code Ann. § 44-7-130 (1976, as amended)), for which the total cost is in excess of that prescribed by R.61-15 and for which specific standards or criteria are prescribed in the State Health Plan.” (See 3.b. below) (Source: Regulation 61-108, *Standards For Licensing Freestanding or Mobile Technology*)

#### **3. Specifically, what does the definition of “Freestanding or Mobile Technology” mean?**

a. Medical equipment owned or operated by a health care facility is exempt from licensing as Freestanding or Medical Technology.

b. Regulation 61-15, *Certification Of Need For Health Facilities And Services*, Section 102.1.f., states that a person or health care facility is required to obtain a Certificate of Need before undertaking the acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of \$600,000.

c. Medical equipment that has a total project cost of \$600,000 or less does not require licensing as Freestanding or Mobile Technology.

d. Currently, only the following medical equipment owned or operated by an entity other than a health care facility could be required to be licensed as Freestanding or Mobile Technology:

1. Positron Emission Tomography (PET and PET/CT) equipment; and
2. Cardiac Catheterization equipment.

**4. What if the medical equipment is owned or operated by a person other than a health care facility?**

If the total project cost is greater than \$600,000 **and** the project has obtained a Certificate of Need **and** specific standards or criteria (as prescribed in the State Health Plan) are met, then the piece of medical equipment would have to be licensed.

**5. What is meant by 'Total Project Cost'?**

Regulation 61-15, *Certification Of Need For Health Facilities And Services*, Section 103.25., defines 'Total Project Cost' as "the estimated total capital cost of a project including land cost, construction, fixed and moveable equipment, architect's fee, financing cost, and other capital costs properly charged under generally accepted accounting principles as a capital cost. The determination of project costs involving leased equipment or buildings will be calculated based on the total value (purchase price) of the equipment or building being leased."