



FREQUENTLY ASKED QUESTIONS

FREESTANDING OR MEDICAL TECHNOLOGY

UPDATED!

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."