



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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COMMISSIONER

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To: All 25 TAC §289.256 Medical Diagnostic Licensees, Generic Exemption No. L16

Subject: Exemption from the requirements of §289.256(v), §289.256(ff)(1), §289.256(hh)(1) and §289.252(r) for procurement, transfer of Tc-99m and calibration of dose calibrators using Tc-99m.

As authorized by §289.201(c), this exemption from certain requirements of 25 TAC §289.256 for medical use licensees is a result of the current shortages of Mo-99. This exemption is issued in order to assure that available Tc-99m will be used for patient administrations. This exemption will remain in effect until the supply of Mo-99 has been stabilized and should only be used for those documented instances where the need for a dose exceeds the supply.

1. In cases where there is a medical need to transfer TC-99m doses between diagnostic nuclear medicine licensees, an exemption from §289.256(ff)(1), §289.256(hh)(1) and §289.252(r) will allow procurement from and transfer to other medical use licensees. However, the licensee must maintain written documentation of shortages from the supplier and the licensee's certification that Tc-99m shortages prevented compliance with §289.256(ff)(1), §289.256(hh)(1) and §289.252(r)

2. An exemption from §289.256(v), the requirements to calibrate dose calibrators within the national recognized standard timeframe and performance of a calibration at the maximum activity, is issued for those instances where Tc-99m is not available in significant quantities for patient administrations and this requirement. The licensee must maintain written documentation of shortages from the supplier and the licensee's certification that Tc-99m shortages prevented compliance with §289.256(v).

This exemption is effective upon issuance and will be in effect while United States shortages of Mo-99 and Tc-99m are documented by suppliers.

Should you have any questions concerning this exemption please contact Scott Kee at (512)834-6688 extension 2212 or Mike Dunn at (512) 834-6688 extension 2207 or by electronic mail at scott.kee@dshs.state.tx.us or mike.dunn@dshs.state.tx.us.

Sincerely,

Michael L. Dunn, Manager
Radioactive Material Licensing Group
Radiation Safety Licensing Branch

Enclosure