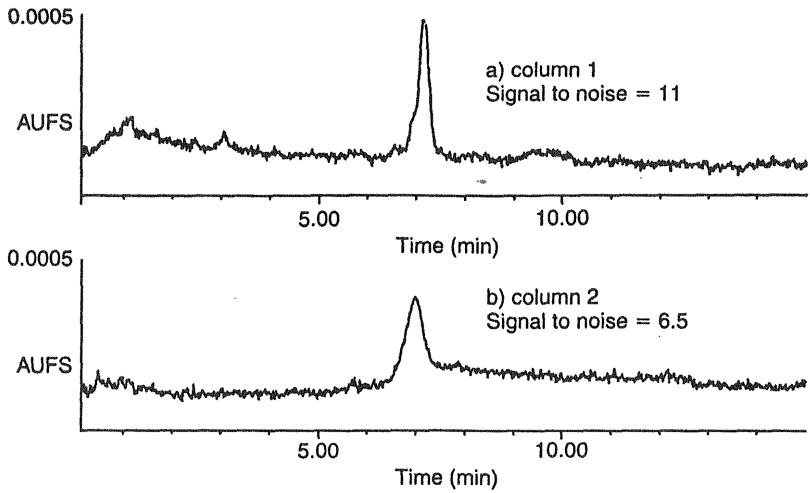

Figure 11.4 Effect of peak shape on LOD and LOQ. (From Ref. 38.)

be based on the standard deviation of the response and the slope. The formula is changed to

$$\text{SD} = 10 \times \frac{\text{SD}}{\text{S}}$$

Determination criteria and requirements for documentation are the same as described under DL in Sec. 17.5, as well as comments by the FDA on the subject. In addition, the FDA Reviewer Guidance recommends that data for analysis repeatability and injection repeatability at the quantitation limit be generated. Further, the Guidance recommends that the use of an additional reference standard at the quantitation limit level be incorporated in the test method.

Additional points regarding the detection and quantitation limits are warranted. These parameters are affected by chromatography. Figure 4 shows the effects of peak shape and efficiency on the signal-to-noise ratio. Sharp peaks will yield a higher signal-to-noise ratio, thus lowering both the DL and the QL. Therefore for the chromatographic determination of these parameters, the age and type of the column and the age of the detector lamp need to be considered. Thus periodic maintenance of the chromatographic detector to maintain optimal results is required.

Finally, the DL and the QL should not be confused with sensitivity. Sensitivity is defined as the slope of the calibration curve, and as such does not usually reference the actual limit of detection or limit of quantitation.

17.7. Linearity

The linearity of an analytical procedure is its ability to obtain test results that are directly proportional to the concentration of analyte in the sample within a given range. Linearity is generally reported as the variance of the slope of the regression