

**41-6a-1621 Departmental hearings -- Compliance of approved devices -- Revocation of approval -- Reapproval.**

- (1) If the department has reason to believe that a part approved under Section 41-6a-1620 should no longer be approved, the department shall, upon 30 days' notice to the applicant to whom approval was issued, conduct a hearing on the question of whether the part should remain approved.
- (2)
  - (a) After the hearing, the department shall determine whether the device meets the requirements of the applicable standard.
  - (b) If the device does not meet those requirements, the department shall give notice to the applicant to whom the approval was issued of the department's intention to revoke the approval.
  - (c) If the applicant to whom the approval was issued fails to satisfy the department that the device being sold or offered for sale meets the applicable standard within 90 days of the notice of the department's intention to revoke the approval, the department shall revoke the approval.
- (3) When an approval has been revoked under this section:
  - (a) the department:
    - (i) shall require the withdrawal of all the parts from the market; and
    - (ii) may require that all devices sold since the notification of the department's intention to revoke the approval be replaced by parts that are approved.
  - (b) A part that has been revoked under this section may not be approved again unless a new application and approval is received.
  - (c) The department may require that as a condition for a new approval of the same or similar part all previously revoked parts are effectively recalled and removed from the market.

Renumbered and Amended by Chapter 2, 2005 General Session