Journal of Dental Technology
August/September 2025 Regulatory Quiz
FDA Regulatory Requirements for Dental Scan Bodies
NBC Approval # 51626

1. The article states that the FDA's Quality System Regulation (QSR) is being aligned with ISO 13485:2016.
    a. True
    b. False

2. Under the updated regulations, all dental laboratories, regardless of size, must maintain a documented quality management system.
    a. True
    b. False

3. The new rule eliminates the requirement for complaint handling procedures in dental laboratories.
    a. True
    b. False

4. ISO 13485 focuses on risk management and traceability throughout the manufacturing process.
    a. True
    b. False

5. The article explains that laboratories producing only custom-made devise are exempt from recordkeeping requirements.
    a. True
    b. False

6. Training records for all personnel involved in manufacturing must be maintained as part of compliance.
    a. True
    b. False

7. The updated requirements emphasize supplier evaluation and control as part of the quality management process.
    a. True
    b. False

8. According to the article, management review meetings should be conducted at least once every five years.
    a. True
    b. False

9. Corrective and preventive action (CAPA) processes are a key element in both QSR and ISO 1485 compliance.
    a. True
    b. False

10. The article states that documentation and record control are critical components for passing FDA inspections.
    a. True
    b. False

Passing quiz grades are worth ½ point documented regulatory standards credit. To earn CDT credit, once the quiz is completed, send it to the NADL at the address or fax number below or submit this quiz online at https://www.nadl.org/jdt-quiz-submissions. To earn an additional ½ point professional development credit, visit www.nbccert.org to submit your time for reading the accompanying article(s) in the professional development log. Quiz credits will appear on the NBC CDT Online Education Tracking System at www.nbccert.org, which is updated weekly. This quiz is provided to test the technician's comprehension of the article's content, and does not necessarily serve as an endorsement of the content by NADL or NBC.

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