

# Regulatory Rumbblings

By Gary Morgan, CDT, and April McDowell

**J**ust like the headline says, there are distinct rumbblings in the regulatory world for dental laboratories these days. Our wish for you is that you be prepared and knowledgeable to handle them. Although these are all mandatory federal requirements essential to providing for a healthy and safe workplace for employees and producing a safe and quality dental device for the patient, the application of the regulations can be confusing.



For this article, we will focus the most recent news from the Occupational Safety and Health Administration (OSHA) and U.S. Food and Drug Administration (FDA) and emphasize items that we repeatedly see as non-compliance issues when we visit laboratories. Let's talk about a few.

The rumblings from FDA are that more dental laboratories are being inspected each year. This includes domestic and offshore facilities. Any dental laboratory may be audited for compliance with the quality system and good manufacturing practice (QS/GMP) requirements of the U.S. Code of Federal Regulations Title 21 Part 820. Several of our clients have been audited during the last couple of years and it is quite a stressful process for any business, especially if they are not prepared.

Let us share with you the experience of one client's audit this last year.

The laboratory was notified about a week in advance that an FDA inspector would be visiting their business. The inspector asked that the laboratory provide, prior to the visit, a copy of the company's policy and procedures manuals for review. Once onsite, the inspector informed the owners of the laboratory that he would probably be in the laboratory for a week. The laboratory was asked to show how they were complying with the quality system requirements by providing documents and records. The management team was asked for documentation to show:

- The competency of the employees for the tasks they performed.
- Ongoing training of employees.
- Approval process for vendors and subcontractors of patient contact materials.
- Purchasing procedures.
- Cleaning schedules for the laboratory.
- Maintenance schedules and repair logs for equipment.

The laboratory had to provide standard operating procedures and work instructions for all manufacturing processes. The inspector asked if the laboratory had performed an internal audit of their quality system and if they had held a management review meeting.

The management representative for the laboratory was challenged by the inspector to show how the laboratory's documents and records fulfilled each section of the QS/GMP requirements. This laboratory and their management representative were up to the challenge and after enduring this detailed scrutiny for nearly five days, the laboratory passed the inspection. Could you? Size does not matter. The laboratory described in the article had around fifteen employees, but FDA has audited laboratories who were one person all the way up to several hundred.

FDA inspectors have very little experience with the business model of the dental laboratory. The making of custom devices one design at a time is a

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departure from a true device manufacturing model which may be more like an assembly line. So with each inspection, the agency learns more and more about how to apply the QS/GMP requirements. Interpretations are constantly evolving and that is the kind of regulatory rumblings that we try to convey in our training sessions.

Many laboratory owners still have not come to grips with the fact that these requirements are not voluntary, it is the law. What is less apparent is that the QS/GMPs can have a very positive effect on the business leading to better quality control, reduced remakes, reduced overhead expenditures and better customer service and retention.

It's not just the FDA that is experiencing changes, OSHA has as well. The enforcement teeth of OSHA are showing under the new secretary of labor and we have been busy at SafeLink Consulting trying to bandage those health and safety bite marks. Let's review some key points for you to look at in your laboratory and possibly avoid citations should OSHA knock on your door.



*“This training must be done initially and every time you introduce a new hazard into the workplace.”*

Let's start with the right-to-know/hazard communication program. This particular OSHA standard addresses how employers communicate both verbally and in writing and how to handle, use, store and dispose of chemicals and other potentially hazardous materials in the workplace to keep employees safe. If you have one or more employees, you must have a fully compliant hazardous materials program including:

- Conducting an assessment of work practices to determine if there is employee exposure to hazardous materials.
- Developing safe work practices to controls these exposures and reduce them to acceptable levels by the following methods. Sometimes you have to do combinations of Nos. 2 and 4 as with infectious materials or silica dust exposures.
  1. Implementing safer substitutes for hazardous chemicals.

2. Installing engineering controls to mechanically remove the hazard.
  3. Employing safe work practices to minimize use and exposure.
  4. Requiring employees to wear personal protective equipment if none of the former methods can reduce the exposure to a safe level.
- Educating your employees about the types of chemicals they work with including how to recognize their presence by sight or odor, how to properly and safely use the material, store it, dispose of it and what the hazard warnings are for each product used. This training must be done initially and every time you introduce a new hazard into the workplace. It also must be documented with the trainers' credentials, subjects covered, employee signatures and date of training.

- Providing access to Material Safety Data Sheets (MSDS) for every chemical you use in the laboratory. You must also have an up to date inventory list of every chemical product in the laboratory and this list should be your index to your MSDSs.

This OSHA standard is really being targeted in laboratories undergoing inspections right now. Did you know that you can be cited on all of the above? Did you also know that laboratories are being cited for not requiring employees to wear chemical goggles whenever using corrosive products? Also, in the above paragraph, under the first bullet point where it states you must conduct an assessment, did you know that includes having air sampling done by an industrial hygienist to determine what your employees' actual exposure level to chemicals like silica dust (investment material, some gypsum products) or methyl methacrylate (monomer) is and if you are under OSHA's permissible exposure limit for any and all established limits?

Other areas OSHA has zoned into are your infection control practices, proper guarding of lathes (both ends), complete documentation of your lockout/tagout program including de-energization procedures for each piece of equipment under your program, complete and thorough documentation of your employee safety training program as well as a comprehensive, laboratory-specific written safety program.

Recently during a seminar at the FDLA's Southern States Symposium & Expo, we kept reminding the audience members that the items listed in our survey are all parts of the safety and quality programs that must be in place at each of their laboratories. The message was received by the attendees because we have personally fielded several calls for clarification since returning from sunny Orlando. Many laboratories simply did not think these regulations applied to them. Remember, if you have one or more employees, you must comply with OSHA. FDA, on the other hand, applies to every dental appliance

manufacturer regardless of whether you are a one-technician show or have several employees.

Compliance is not an option and none of us like being told we have to do it, but your adherence to these regulations can bring benefits if done right. A quality system compliant with the FDA's Title 21, Part 820 has been proven to reduce remake rates

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and costly errors savings thousands of dollars to some of our clients. An effective health and safety program can reduce worker's compensation costs and lost productivity and can improve employee morale. So, quiet those rumblings you're hearing by getting on board with compliance. You'll be glad you did. 📌

#### About the Authors:

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## focus Magazine Article Quiz 3rd Quarter 2010

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(NBC Approval #: 21241 , FDLA Approval #: )

1. The mandatory federal requirements are essential in order to for a technician to produce a safe and quality dental device for the patient.
  - a. True
  - b. False
2. According to the FDA, only domestic laboratories will be subject to inspection.
  - a. True
  - b. False
3. In the example stated in the article, how much notice was the laboratory given that the FDA would be inspecting them?
  - a. 1 day
  - b. 1 week
  - c. 2 weeks
  - d. 1 month
4. Which of the following documentation materials was not asked for during inspection?
  - a. Ongoing training of employees.
  - b. Purchasing procedures.
  - c. Employee's social security numbers.
  - d. Competency of employees for the tasks they performed.
5. How many people did the laboratory in the case presented employ?
  - a. 1
  - b. 15
  - c. 50
  - d. 150
6. QS/GMPs can lead to all of the following except:
  - a. Better quality control
  - b. Reduced remakes
  - c. Better customer service
  - d. QS/GMPs lead to all of the above
  - e. Qs/GMPs lead to non of the above
7. What is the name of the program OSHA is enforcing?
8. Which two safe work practices do you have to employ when handling infectious materials or silica dust exposed materials?
  - a. Implementing safer substitutes for hazardous materials.
  - b. Installing engineering controls to mechanically remove the hazard.
  - c. Employ safe work practices to minimize use and exposure.
  - d. Require employees to wear personal protective equipment if none of the former methods can reduce the exposure to safe level.
9. OSHA applies to every dental appliance manufacturer regardless of whether you are a one-technician or have several employees.
  - a. True
  - b. False
10. An effective safety program can reduce worker compensation costs, lost productivity and improve employee morale.
  - a. True
  - b. False

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