Implementing a

Cost-Effective Quality Sharps Management Program

A Compliance Guide From

HealthFirst®

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Overview

All practices using sharps are liable for their proper containment and ultimate disposal.

Healthcare professionals are faced with a wide array of regulations and industry recommendations as to best practices or standard of care. Most of these are designed to protect their patients, such as autoclave testing to ensure instrument sterility. Others are meant to protect the community, so that mercury amalgam and expired medications do not enter the municipal waste water stream. Finally, some are for employees' protection (e.g. staff wear gloves and masks so they don't become patients themselves nor contaminate a patient.)

Sharps management is one of the few areas covered by multiple agencies, because the dangers of needlesticks are so well documented and because of the potential risks to patients, staff, and the community.

Sharps containers themselves are a class II medical device, regulated by the FDA. They are considered to be an "engineering control" under the Needlestick Safety and Prevention Act of 2000, which requires all healthcare providers to develop exposure control plans to minimize the potential for needlesticks and update those plans annually with input from frontline healthcare workers.

The law also requires OSHA to enforce compliance. NIOSH has guidelines for selection criteria and placement, to minimize both manipulation and transport, and to keep inquisitive visitors or unattended children from harm.

Federal and state EPA's regulate proper disposal of sharps and medical waste. Whether a land service picks up the waste on a contracted schedule, or the office chooses the convenience and savings of a self-managed return shipper via UPS or USPS, the generator is responsible for proper packaging and for maintaining documented proof of treatment and disposal. The kits are built and tested to rigorous standards for secure over-the-road transport to DOT requirements.

Selection of the optimal sharps recovery service program is essential for patient, staff, and community safety. The consequences of adverse publicity in the event of a violation, injury, or outbreak could be devastating to any vibrant practice. This guide reviews the factors one should consider in selecting the optimal service and in developing a Sharps Management Program as a critical component of the overall practice Quality Plan.

Safety in the Practice

Protect your patients and staff.

Given the well-documented potential for occupational exposure and the transmission of life-changing viruses through accidental needlesticks to and from patients, every healthcare provider has a fundamental responsibility to manage sharps waste safely.

The ADA principals, including beneficence and nonmaleficence, are typically sworn in dental school; however, despite decades of evolving technology and industry education, serious incidents still occur with alarming regularity.

This next section will explore further the ramifications of imperfect sharps management to the practice, the patients, the staff, and the community along with the specific regulations that have been instituted to ensure compliance and the health of each constituency.

Did you know?

The CDC estimates over 1000 needlesticks daily in US hospitals alone, with half or more of all injuries unreported. [1]

Safety in the Practice

Keep your patients safe: one needle, one carpule, one patient.

The vast majority of sharps-related injuries in the dental setting are the result of inadvertent sticks. But accidents do occur when simple best management practices for patient safety are not followed.

- Containers should be placed out of reach of children – never on the floor
- Do not leave sharps unattended in the operatory or elsewhere
- Do not carry uncapped sharps through walkways used by patients

One needle, one carpule, one patient.

Core Principles for Patient Safety:

- Keep sharps out of patient reach
- Place sharps containers out of children's reach
- Never reuse a syringe or medicament

Did you know?

Since 1999, over 125,000 patients have been notified of potential exposure to HBV, HBC, and HIV due to unsafe injection practices. [2]

Safety in the Practice

Keep your staff safe.

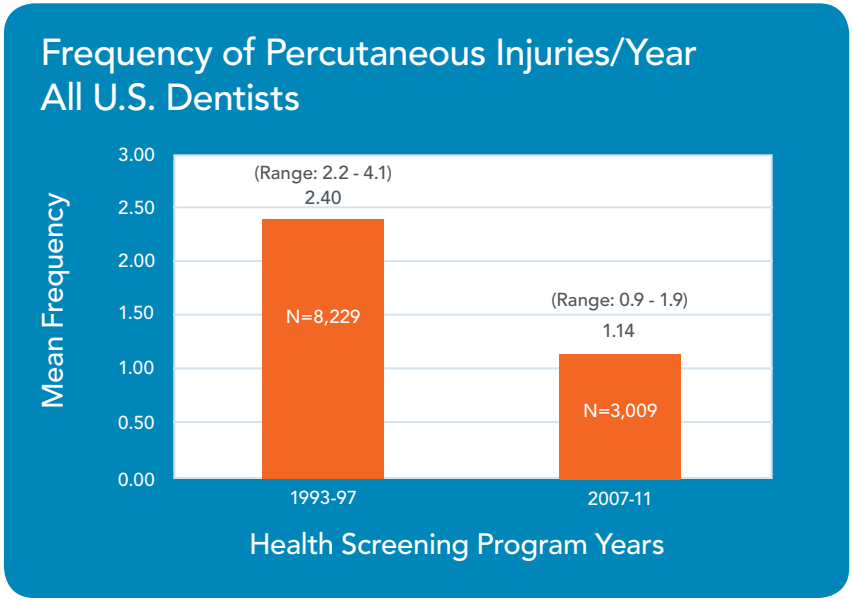
Healthcare professionals providing comfort and care have encountered life-changing experiences from accidental exposures. The Needlestick Safety Act of 2000 formalized prior CDC guidelines and required OSHA to revise and enforce its Bloodborne Pathogens (BBP) Standard to protect all employees likely to come in contact with blood or other potentially infectious materials.[3,4]

Key Staff Safety Requirements in the Needlestick Safety Act of 2000:

- Annual BBP training of all employees
- Access to PPE including gloves, gowns, masks, etc.
- Development and annual review of an exposure control plan by frontline healthcare workers (staff)
- Consideration of engineering controls (which includes sharps containers and safety versions of syringes, scalpels, etc.)
- Documentation that the plan has been fully executed.

As a result of the Act and increased compliance, needle stick injuries in dentistry have decreased dramatically. [5,6]

However, needlestick injuries continue with alarming regularity and data from the ADA Health Report suggests there are approximately 140,000 percutaneous injuries in dentistry each year, and countless more unreported.



Safety in the Practice

Liability and implications for needlestick injuries.

While exposure to a patient or employee is devastating in and of itself, the repercussions to the practice are significant.

Patient exposure is considered to be a "never event" meaning that the practice is totally responsible for restoring the health of the patient, non-reimbursed. This includes all testing and prophylactic treatment even if there is no seroconversion. Similar obligations apply if the employee becomes a patient through an accidental needlestick, with initial baseline testing and treatment costs estimated at up to $3000. [7]

Other negative consequences to the practice include potential fines and penalties, up to and including loss of licensure, adverse publicity, and challenges in renewing insurance policies.

Safety in the Practice

Community safety.

Syringes and medications that fall into lay hands are a danger to the community; therefore, Federal and state EPA have aggressively regulated and monitored compliance with proper disposal of used sharps.

Not only is it illegal to mix potentially infectious sharps with other waste streams, it is also illegal for anyone other than a licensed transporter to move sharps containers, and only in approved shipping cartons or systems. Licensed medical waste haulers maintain licenses with the DOT. The USPS® permits mailback systems for both sharps and "red bag" medical waste documented to have passed stringent test requirements. UPS accepts sharps kits tested to the USPS protocols.

When sharps containers have been found in dumpsters or other inappropriate locations, local authorities have been extremely diligent in tracking down the generator and enforcing applicable penalties.

What are Sharps?

A sharp is anything that can pierce skin.

Per the bloodborne pathogens standard, any disposable medical device that can pierce skin is considered to be a sharp and must be disposed of in an approved sharps container immediately after use. This would include needles and syringes, scalpels, blades, broken glass, etc.

In a dental practice this would include dental needles, anesthetic carpules, and exposed ends of orthodontic wire.

Reusable instruments are to be sterilized and repackaged after each episode of care.

What is Medical Waste?

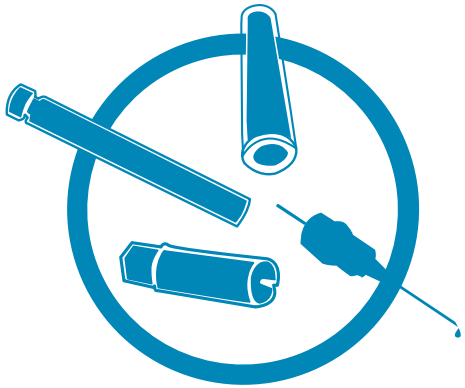
Anything caked or saturated with blood or body fluids is considered medical waste.

The bloodborne pathogens standard defines regulated waste as liquid or semi-liquid blood or Other Potentially Infectious Material (OPIM); contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious material.[8]

Non-sharps medical waste is typically isolated in red bags, clearly marked with the biohazard symbol, and aggregated for subsequent treatment and disposal along with filled sharps containers.

The OSHA distinction limiting medical waste to items saturated or caked with body fluids is critical in developing a Compliance Plan which is both compliant and cost-effective. Many practices have been falsely guided into treating all gloves, masks, and patient bibs with any visible blood as medical waste. With the obvious exception of oral surgery, most dental practices should not generate significant medical waste beyond the dental needles used for delivering anesthetic, and should not require expensive scheduled route service by a medical waste hauler.

What Goes into a Dental Sharps Container?



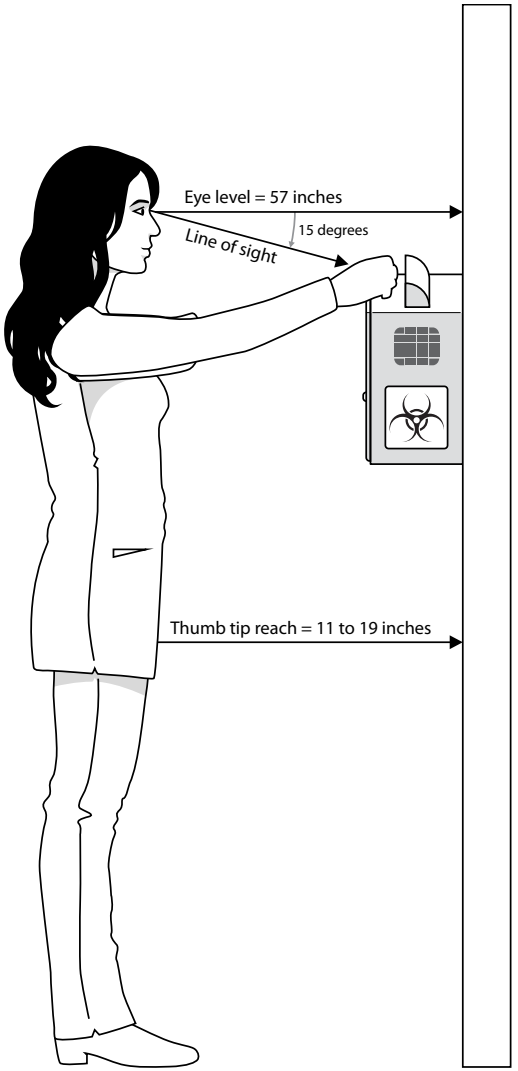
Use approved containers for the recovery of sharps, needles and lancets.

- Dental needles and caps
- Needles, blades, lancets, suture needles
- Anesthetic cartridges (glass carpules) that are broken or contain blood
- Broken glass with blood on it
- Syringes
- Any vials with trace amounts of blood
- Used epinephrine auto-injectors
- Burs/Diamonds
- Retaining bands and orthodontic wire
- Extracted teeth not containing amalgam fillings
  (Teeth with amalgam should be disposed of in approved amalgam waste containers)

Never put loose sharps in medical (red bag) waste containers.

Container Location

Place containers as close to the work area as possible to minimize handling.



NIOSH developed clear recommendations for product selection and placement.[9]

For staff protection, the most important criteria are that the sharps container should be placed as close to the site of use as practicable and have a clear entry path for disposal with minimal manipulation. For patient/visitor protection, the containers should not be left accessible to inquisitive siblings.

An ideal standing installation height for a fixed sharps disposal container is 52 to 56 inches.

This height will comfortably accommodate 95% of all adult female workers. [9]

Selecting the Optimal Containers for my Practice Requirements

Frequency of use and change out drive ideal capacity decision.

Most dental practices will choose to place a 1-quart container in each operatory room so that the assistant can position it on or near the instrument tray during anesthesia and move it safely out of harm's way post-procedure. Alternatively, wall-mounted 5-quart containers are another popular alternative, as they have built-in engineering controls which prevent anyone from reaching the contents below the fill line once properly disposed. Others choose to create countertop access holes for 2-gallon or 3-gallon containers inside of a countertop. Each of these would be compliant solutions.

Recognizing that there ought to be a sharps container in each operatory, the final decision factor should be the desired frequency of exchange.

Approximate container capacities:

1 qt.: 70 carpules and 50 dental needles (35-40 patients)

5 qt.: 300 carpules and 200 dental needles (150-175 patients)

2 gal.: 560 carpules and 400 dental needles (280-320 patients)

3 gal.: 840 carpules and 600 dental needles (420-480 patients)

Stay Compliant with Local Requirements

Understand your local regulations regarding storage of sharps and non-sharps.

Certain states and counties have specific allowable storage times for sharps and non-sharps (e.g. blood-soaked gauze). Some states calculate storage times beginning from initial use, while others calculate from the time the container is full.

Use specific sharps container sizes that can cater to your practice needs to maximize the capacity of the container while remaining compliant with local regulations pertaining to sharps and non-sharps storage timelines.

State	Allowable Storage Time for Sharps	Allowable Storage Time for Non-Sharps (i.e., bloody gauze)
Arizona	90 Days once full	90 Days once full
Arkansas	30 Days once full	30 Days once full
California	30 Days once full	30 Days from date of initial use (Small waste generators who generate less than 20 lbs/mth)
Florida	30 Days once full	30 Days from date of initial use
Michigan	90 Days from date of initial use	30 Days from date of initial use
Mississippi	No time limit	7 Days once full
New Hampshire	72 Hours once full	72 Hours once full
Nevada (Washoe County)	30 Days once full	7 Days once full (Must date outer container)
New Jersey	1 Year from date of initial use	1 Year from date of initial use
Pennsylvania	30 Days once full	30 Days from date of initial use
Rhode Island	No time limit	7 Days once full
South Carolina	14 Days once full	14 Days once full
Virginia	7 Days once full (container must be dated)	7 Days once full (container must be dated)
West Virginia	30 Days once full	30 Days from date of initial use
Wisconsin	At least every 90 Days	At least every 90 Days
All Other States	No time limit	No time limit
All States	Dispose immediately if waste begins to smell	Dispose immediately if waste begins to smell

For information purposes only
Customer is responsible for determining and complying with any applicable local, state, and federal legal and/or regulatory requirements.

Container Monitoring

Check container fill levels frequently and replace when contents approach the fill line.

Selecting the appropriate containers for the practice activity is an essential first step; however, no container replaces itself when full. Someone needs to be assigned to check the fill level of every sharps container on a regular basis, and to replace the container when it is approaching the marked fill line or likely to reach that level before the next scheduled inspection. Alternatively, in states with time limitations on used sharps containers, they should be replaced on a predetermined date regardless of fill level.

The monitoring and exchange process needs to be a core component of the practice's Sharps Management Program, incorporated into a comprehensive Exposure Control Plan as required by the 2000 Needlestick Safety Act.[8] This law requires staff involvement in the product selection process and at least an annual device review to allow for consideration of newer, safer, engineering controls. Sharps containers are considered an engineering control.

OSHA has developed model exposure control plans and made them available online, although specifics should be customized by every practice for their unique requirements.

https://www.osha.gov/Publications/osha3186.pdf

To assist in documenting compliance with the sharps monitoring responsibility, these tasks can be assigned, scheduled and tracked as part of the complimentary HealthFirst OnTraQ™ program. The process is similar to weekly spore testing of each autoclave.

Annual plan review, and annual bloodborne pathogens training, are additional practice tasks that can be readily assigned, scheduled, and tracked for compliance via the OnTraQ tool. In the event of an OSHA inspection this documentation is your proof of compliance.

OSHA Best Management Practices

A quality checklist for sharps handling and disposal.

☑ Convenience	Containers should be conveniently placed where sharps waste is generated. Centralization is not recommended, due to the risk associated with moving sharps waste from one place to another within the practice. Place a sharps container in every operatory.
☑ Accessibility	Containers should be easily operated with one hand and have obstructed openings, so that no one can reach inside.
☑ Management	Containers should be plainly visible to staff that use them, and should be able to see the degree to which the container is full.
☑ Safety First	Containers should always be placed out of reach of children, never on the floor.
☑ Championship	Designated staff should monitor the fill level of all containers, prohibit placement of non-sharps waste in a sharps container, and ensure that all staff are educated in proper sharps disposal.
☑ Responsibility	Never force sharps waste into an already full container, as this may lead to a needle stick injury and/or container failure.
☑ Appropriate Use	Do not place amalgam, hazardous waste, or other inappropriate waste in a sharps container. Each dental waste stream is unique, requiring conscientious handling by staff, and responsible disposal by waste recovery services.
☑ Prompt Disposal	Do not retain sharps waste on site. Always dispose of waste properly and in a timely fashion through a licensed medical waste recovery service.

OSHA Best Management Practices—based on NIOSH 1998 Research Document (research agency for OSHA and CDC)

Selecting the Appropriate Disposal Solution

Economics and flexibility drive disposal decision.

All generators are legally responsible for their sharps waste and/or medical waste throughout the transport and disposal phases until they receive documented proof of treatment by receipt of a signed copy of their original manifest.

Whether one contracts for scheduled pickups from a land service provider or opts for a mail-back sharps disposal kit that includes return shipping via USPS® or UPS®, the key factors are comparable: the generator is responsible for properly packaging the carton for pick-up or mailing and must attest to the contents by signing the original manifest. The disposal provider, or disposal partner of the kit provider, will be licensed and heavily regulated by federal, state and local EPA. They will provide documentation of treatment and disposal shortly after receipt, generally electronically.

The true decision factors are largely economic. Self-managed programs allow the generator to fill a package to capacity and decide when to have their waste processed. The package can be handed to the UPS driver or postal carrier, although the method of return shipment is specified at the time of purchase. USPS will accept both sharps waste and medical waste. UPS only accepts sharps waste; however, as noted earlier, few dental practices generate significant non-sharps medical waste.

Some “mail-back” services include auto-replenishment, others do not unless pre-authorized. Some mail programs offered by land service providers also require a contract and have “account maintenance fees” if the product is not returned and a new one purchased on a periodic basis.

Contracted Service Considerations

Long term contracts and surcharges may prove regrettable.

Major land service providers typically require a long-term contract, often auto-renewing, with uncapped price escalators and additional fees to protect their interests (e.g. fuel service charges.) The fee may be monthly but the service bi-monthly or quarterly to suit their route structures. The fee is a minimum even if less waste is generated than what was anticipated when the rate was set; however, surcharges apply if additional boxes are picked up. The model is not dissimilar from cell phone plans, with fixed fees and early termination charges coupled with overage fees.

Some firms also effectively shift liability to the generator by contractually requiring agreement with the service provider's waste acceptance policy.

Some mail programs offered by land service providers also require a contract and have "account maintenance fees" if the product is not returned and a new one purchased on a periodic basis. The contract may include auto-replenishment, others do not unless pre-authorized.

Bottom Line

Read the fine print before contracting. Do the math, and know your window to terminate. Some contracts have very narrow windows to cancel, often well before expiration, and service changes may also trigger auto-renewal, potentially for as many as five additional years.

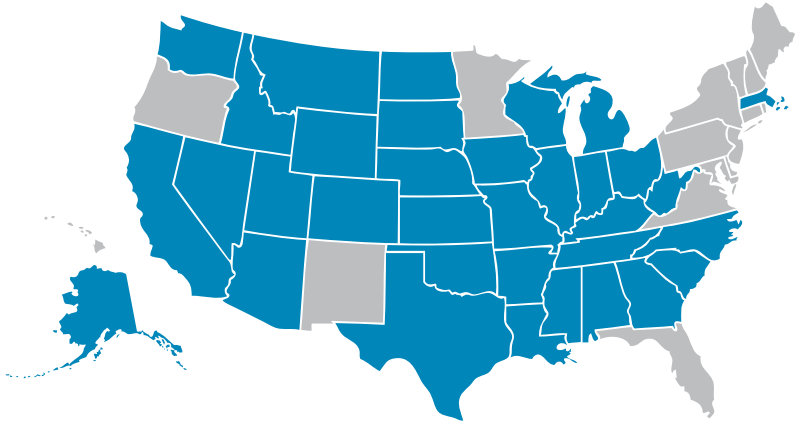
On-Site Treatment

Regulatory, liability, and consistency issues limit this alternative.

A third alternative to mail-back services are on-site treatment kits that contain a sharps container partially filled with a proprietary solution designed to disinfect and solidify the sharps waste once activated. Once these sharps containers are solidified, the contents are considered "decontaminated solid medical waste," and in some states, can be disposed of in the regular trash.

There are several drawbacks to this option. Most importantly, there is no 3rd-party documentation of sharps waste processing and disposal, releasing the generator of their liability, so the practice remains potentially liable for its sharps waste indefinitely. Furthermore, activation of the solidifier may be somewhat inconsistent, because the manufacturer recommends pouring dental cement into the container if the contents are not completely hardened. Also, capacity is difficult to compare as a portion of the container is already filled with liquid.

Lastly, disposal of this type of product as "regular office trash" is only allowed in certain states.



= Able to use this method

= Unable to use this method

Only offices in the states shown in blue can legally use this type of service. Be sure to check you local regulations regarding on-site treatment solutions.

Sharps Waste Tracking and Processing Certifications

Retain your documents of disposal.

Whether you choose to use a local pickup service, mail-back service, or other sharps recovery services designed to meet the regulatory requirements of the OSHA Blood-borne Pathogen Rule 29CFR 1910.1030, ensure that these services can provide you with the proper documentation for waste tracking and disposal certifications.

As the generator of the sharps and medical waste, it is important that you understand that you are responsible for the safe transport of that waste until it is received by the waste processor for proper treatment and disposal/destruction.

When your sharps and medical waste are transported or mailed off-site, retain a copy of the manifest tracking form if required by your state (usually 2-5 years.) Proof of destruction can be provided to your office as a hard copy or in an electronic manifesting system. When electronic methods are chosen for manifest documentation and archiving, it's more environmentally friendly.

Developing a Comprehensive Exposure Control Plan

All practices must develop, implement, and annually update an Exposure Control Plan.

The Needlestick Safety and Prevention Act of 2000 requires all healthcare providers to develop exposure control plans to minimize the potential for needlesticks and update those plans annually with input from frontline healthcare workers. The law also requires OSHA to enforce compliance.

This law requires staff involvement in the product selection process, and at least an annual device review to allow for consideration of newer, safer engineering controls. Sharps containers are considered an engineering control.

Product selection and placement, the monitoring and exchange process, and the disposal solution are core components of the practice Sharps Management Program, preferably incorporated into the comprehensive Exposure Control Plan as required by the 2000 Needlestick Safety Act.

OSHA has developed model exposure control plans and made them available online, although specifics should be customized by every practice for their unique requirements.

https://www.osha.gov/Publications/osha3186.pdf

Implementing a Comprehensive Exposure Control Plan

An automated tool can facilitate documentation that recurring compliance tasks are assigned and completed.

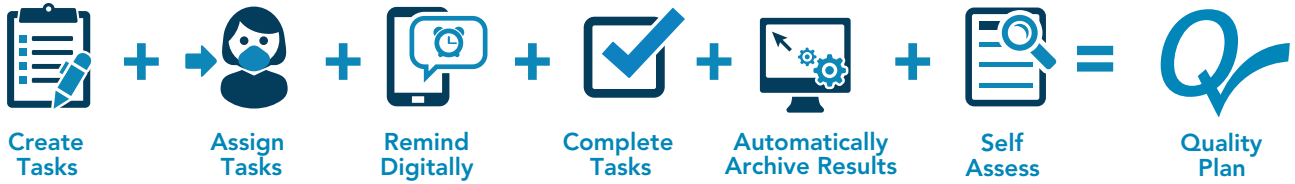
Once the fundamental decisions are made regarding product selection, placement, and the disposal solution, an automated tool can facilitate documentation that recurring compliance tasks are assigned and completed.

In the event of an OSHA inspection, these digital records are your proof of compliance.

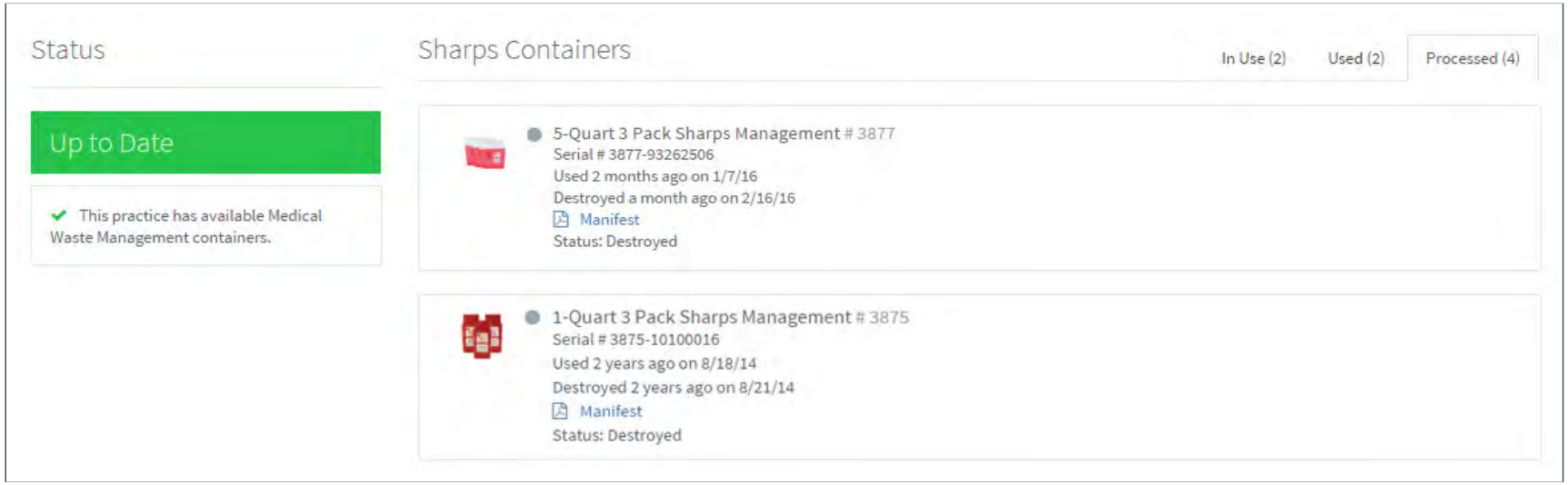
Examples of Exposure Control Plan tasks include annual BBP training and online recertification testing, annual plan review for best practices, etc.

Examples of Sharps Management Program tasks include scheduled (e.g. weekly) inspections of each sharps container, exchange as appropriate or required by state EPA, packing and manifesting of the waste, and archiving of the return manifest.

Master Compliance Equation



OnTraq is an online compliance task management solution that helps dental practices effectively manage operational tasks and keep their practice in compliance with OSHA, HIPAA, and the CDC - Possibly saving the practice thousands of dollars in violation fines, and the loss of license to practice dentistry. OnTraq gives you peace of mind knowing that all business critical tasks are taken care of.



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Tracking ID
1005940-10258629

WASTE MANIFEST - TRACKING DOCUMENT

TRACKING MANIFEST DIRECTIONS FOR GENERATOR:

1. Complete sections 1 through 5 on this duplicate form
2. Make sure that item 3 (Signature of Generator) has been signed
3. Keep bottom (Generator) copy for your records
4. Place top copy back in the ziplock bag on the side of the box and seal bag

All Items below must be filled out completely by the generator:

Happy Smiles DDS	**Sharps Waste**
1. Generator - Printed name	4. Description of Contents
4502 Main Street	3/26/16
2. Street Address	5. Date of Shipment
AnyTown PA 30045 USA	
City, State, Zip	
474-555-1526	"By signing this I certify that this container has been approved for the shipping of used sharps in accordance with the directions for that purpose. I am aware that full resposibility rests with the generator for any violations of 18 USC 1716 which may result from placing improperly packaged items in the shipment. I also certify that the contents of this container are fully and accurately decribed above by proper shipping name and are packed, marked, and labeled, and in proper condition for carriage according to the applicable national governmental regulations"
(area code) Telephone	
3. Signature of Generator	

GENERATOR COMMENTS:

(THIS SECTION IS TO BE COMPLETED BY PROCESSOR SITE ONLY)
"I certify that the contents of this container has been recovered, treated, and processed in accordance with all local, state, and Federal regulations"

PROCESSING FACILITY	PROCESSING FACILITY REPRESENTATIVE
Medical Waste Services 7321 Quimby Street Paramount, CA 90723	Print Name: JOHN SMITH Signature: Date: 4/1/2016
Facility Permit: OST/TS #94	

IN CASE OF EMERGENCY OR DISCOVERY OF DAMAGE OR LEAKAGE
CALL 1.855.563.8285

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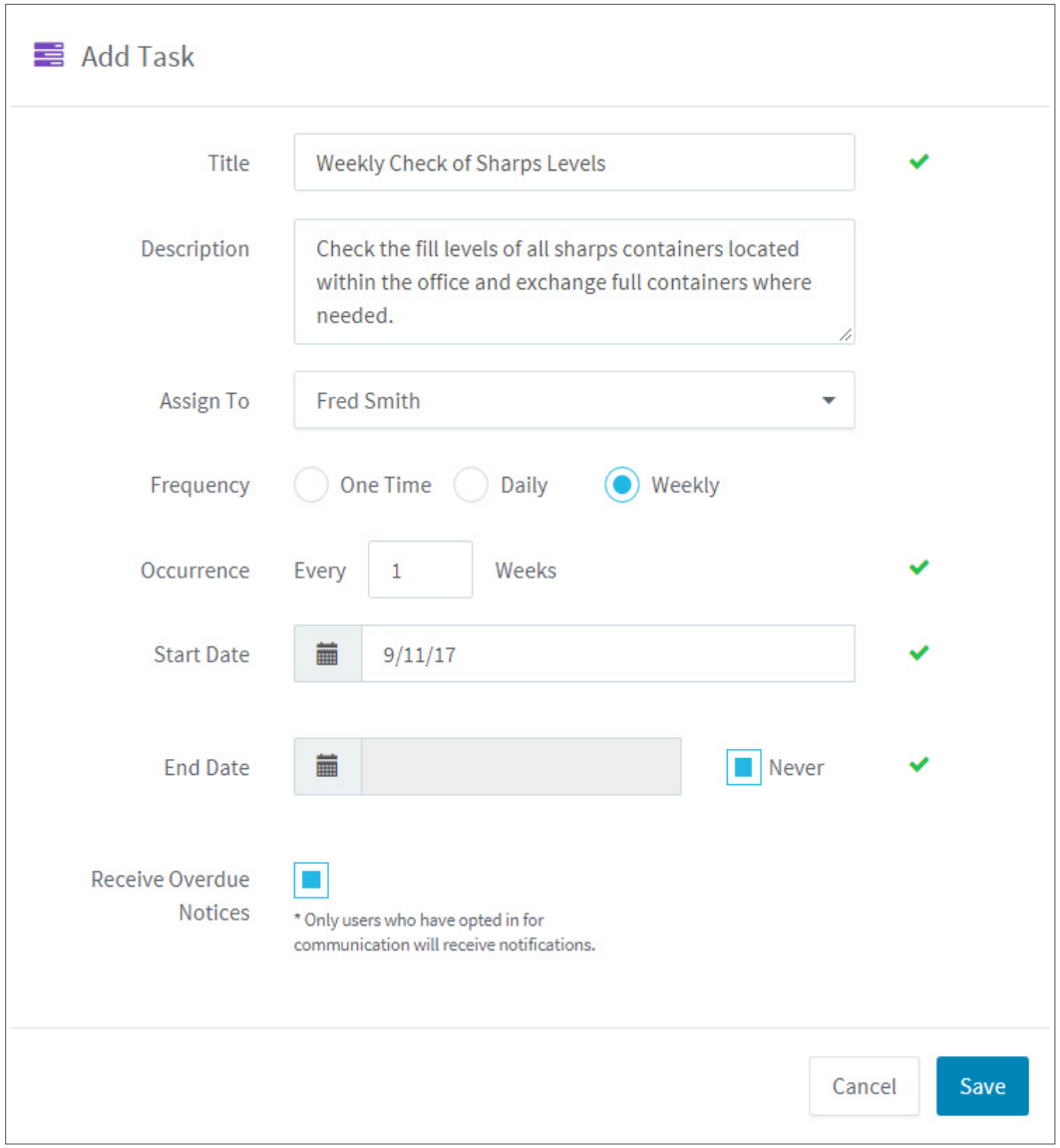
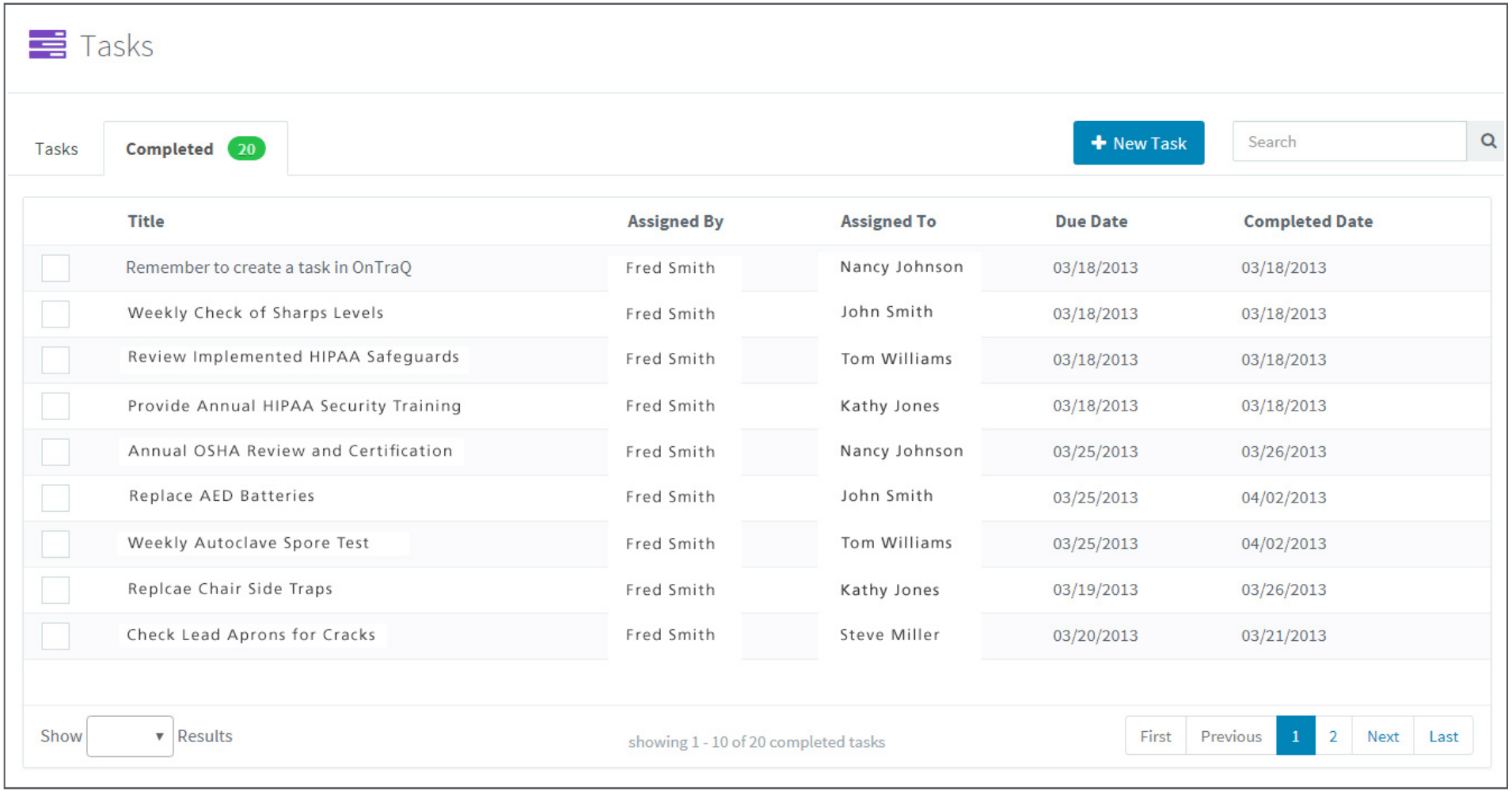
Bottom Copy (Generator) / Top Copy (Processor / Archive Copy)

Monitor the destruction lifecycle of your unused medications, sharps, and medical waste.
Know exactly when something was received and destroyed by our network of waste destruction partners.
Confirm destruction manifests to ensure accuracy and maintain an audit trail for your practice.



Create tasks, assign them to staff members, and control how often a task will repeat.

Get things in your office done efficiently and on time. Manage your own tasks, or your practice's tasks. Get email and SMS text notifications about tasks. Overdue tasks generate notices to the office administrator.



Practice, Patients, Planet

Ensure you're protecting these three facets equally.

No other single facet of a comprehensive Quality Plan is as actively regulated as Sharps Recovery. OSHA monitors compliance for staff protection from blood-borne pathogens and needle sticks. Careful consideration must be given to product selection and placement to also protect patients and visitors from accidental injury and exposure. EPA regulations protect the local community and the nation, by requiring the generator to maintain responsibility until the sharps are ultimately treated and disposed.

Despite these daunting regulatory requirements, simple, cost-effective, solutions are available and the monitoring tasks documented with complementary software solutions. By design, OSHA requires staff involvement in the product design process, and together, each practice will arrive at the appropriate and responsible solution for their practice, their patients, and their planet.

Summary

A quality Sharps Management Program requires consideration of many elements, but can be readily maintained.

By using the information in this compliance guide, you will have learned:

- Staff, patient, and community safety are heavily regulated due to the serious risks of disease transmission through accidental needlesticks
- A systematic approach involves the staff in product selection and placement.
- Selecting the right containers for your practice takes into account the quantity and size of sharps you generate
- Regular fill-level inspection and exchange is required
- There are clear alternatives for disposal and treatment, with significant economic consequences
- Documenting execution of all of the plan elements is essential to satisfy regulators and potentially practice insurance carriers
- Compliance software programs are a convenient way to digitally store all of your records and proof of compliance
- You must annually review the plan to ensure best practices with evolving technology and local requirements.

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About the Author

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Chief Compliance Officer
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Dr. Donald Cohen, a trusted figure and key opinion leader, has been a licensed and practicing dentist for over 30 years. Additionally, Dr. Cohen has 20 years of teaching experience at Columbia University SDOS, and 20 years as an Attending Dentist at Columbia Presbyterian Hospital in New York City.

Dr. Cohen is former President of the New York State Society of Dentistry for Children, and currently acts as Director of Compliance for Health Compliance Team, Inc., a national compliance company that delivers numerous compliance seminars and total on-site solutions to dental practices.

With his many years of experience in the field and in the classroom, "Dr. Don" is an expert in the areas of dental compliance, regulations, and best practices.

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- **Infection Prevention**
- **Environmental Recovery**

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