HHE HealthHazard® Evaluation Program

Evaluation of Exposures to Dust and Noise at a Pharmaceutical Manufacturing Facility

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Introduction

Request

Management at a pharmaceutical manufacturing facility requested a health hazard evaluation of employees' exposures to pharmaceutical dust and noise during pharmaceutical manufacturing.

Workplace

The facility was a single-story building that had been operating at the same location since the mid-1990s. At the time of our site visit, there were nine production employees—three in the clinical manufacturing section, and six in the clinical materials management section. Production employees mainly prepared and packaged pharmaceuticals for use in clinical trials. Most of the pharmaceuticals were placebos and did not contain any active pharmaceutical ingredients. Workers entered the production area through the gowning room, where they put on (donned) and took off (doffed) personal protective equipment. The clinical manufacturing section included the over-encapsulation room, the tablet-coating room, the tablet press room, and the capsule filling room. The clinical materials management section included automated bottle packaging and blister card packaging rooms. Each room in the production area was separately ventilated. Most rooms were kept under positive pressure relative to their anterooms (small room leading into a main room).

To learn more about the workplace, go to Section A in the Supporting Technical Information

Our Approach

We measured and evaluated employees' exposures to particulates and noise in the pharmaceutical manufacturing and packaging areas. These employees worked in the clinical manufacturing, clinical materials management, and biopharmaceutical laboratory sections of the facility. We conducted a virtual walkthrough of the facility in April 2022. In November 2022, we visited the facility and completed the following activities:

- Observed work processes, work practices, and conditions.
- Measured particulates in air during pharmaceutical manufacturing and packaging.
- Took full-shift personal noise exposure measurements from workers involved in manufacturing and packaging pharmaceuticals. We calculated noise exposures using time-weighted averages, which takes into account the varying levels of noise throughout the entire workday.
- Measured sound levels throughout the manufacturing and packaging areas of the facility.

To learn more about our methods, go to Section B in the Supporting Technical Information

Our Key Findings

Dust levels were below occupational exposure limits

- During some work activities, respirable dust levels, which are the levels of dust the lungs breathe in, could be very high for short periods of time.
- During tablet pressing, hand-scooping powder generated the highest dust levels compared with other tasks we measured.

Employees' full-shift noise exposures were below noise exposure limits

- Employees working in the bottling room had the highest noise exposures. Depending on how much time they spent on high noise tasks, such as using compressed air to clean equipment, their noise exposures could increase.
- The highest sound levels occurred when employees used compressed air.

To learn more about our results, go to Section B in the Supporting Technical Information

Our Recommendations

The Occupational Safety and Health Act requires employers to provide a safe workplace.

Potential Benefits of Improving Workplace Health and Safety:

- ↑ Improved worker health and well-being
- ↑ Better workplace morale
- ↑ Easier employee recruiting and retention
- ↑ Enhanced image and reputation
- ↑ Superior products, processes, and services
- ↑ Increased overall cost savings

The recommendations below are based on the findings of our evaluation. For each recommendation, we list a series of actions you can take to address the issue at your workplace. The actions at the beginning of each list are preferable to the ones listed later. The list order is based on a well-accepted approach called the "hierarchy of controls." The hierarchy of controls groups actions by their likely effectiveness in reducing or removing hazards. In most cases, the preferred approach is to eliminate hazardous materials or processes and install engineering controls to reduce exposure or shield employees. Until such controls are in place, or if they are not effective or practical, administrative measures and personal protective equipment might be needed. Read more about the hierarchy of controls at https://www.cdc.gov/niosh/topics/hierarchy/.

We encourage the company to use a health and safety committee to discuss our recommendations and develop an action plan. Both employee representatives and management representatives should be included on the committee. Helpful guidance can be found in *Recommended Practices for Safety and Health Programs* at https://www.osha.gov/shpguidelines/index.html.

Recommendation 1: Reduce airborne dust exposure as much as possible

Why? Reducing the amount of dust in the air, which in this case is coming mostly from placebo manufacturing, would help keep eyes and nasal passages from getting irritated [NIOSH 2004].

Sometimes employees used powder that contained active pharmaceutical ingredients. Exposure to this dust can cause health problems like allergic reactions and upper respiratory irritation [NIOSH 2011]. While our results show that manufacturing at this facility is not a very dusty operation, it is still best practice to reduce airborne dust especially when containing active pharmaceutical ingredients.

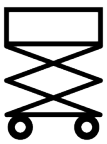
How? At your workplace, we recommend these specific actions:

Stop using compressed air to blow dust and powder off clothing. Use compressed air as little as possible when cleaning equipment.

- Use a vacuum equipped with a high efficiency particulate air or HEPA filter to clean dust on surfaces.
- Make sure the filter in the vacuum is HEPA-certified and properly seated (fitted) in the vacuum.

Reduce or stop hand scooping powders.

- Consult with an engineer to identify work processes that can be changed to allow bulk powders to be handled in closed systems rather than manually scooping from open containers.

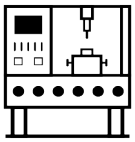


Provide tables that adjust to different heights to reduce the distance that employees need to move powder from containers to hoppers.

Recommendation 2: Reduce potential exposure to noise in the workplace

Why? Noise-induced hearing loss is a permanent condition that gets worse when exposed to loud noise. Unlike some other types of hearing disorders, noise-induced hearing loss cannot be treated medically. Noise-exposed workers can develop substantial noise-induced hearing loss before the problem is realized.

How? At your workplace, we recommend these specific actions:



Eliminate the use of compressed air in pharmaceutical manufacturing and packaging equipment.

- If elimination is not possible, use compressed air nozzles designed to generate less noise.

Continue to use hearing protection during work activities with high noise levels and any time compressed air is used.

- The employee bleeding nitrogen from the tank should wear both earplugs and earmuffs.

Recommendation 3: Address other health and safety issues we identified during our evaluation

Why? A workplace can have multiple health hazards that cause worker illness or injury. Similar to the ones identified above, these hazards can potentially cause serious health symptoms, lower morale and quality of life for your employees, and possibly increase costs to your business. We saw the following potential issues at your workplace:

- A near miss was observed where an employee was almost hit in the head by an unsecured overhead compressed air nozzle.
- An employee was chewing gum in the bottling room of the production area.
- An employee used a rolling chair as a stepstool.
- An employee stood on the very top of a stepladder while attempting to reach something.
- Employees did not always wear safety glasses when using compressed air.
- Employees did not wear protective footwear when changing out the drums of the tablet-coating machine.

Although they were not the focus of our evaluation, these hazards could cause harm to your workers' health and safety and should be addressed.

How? At your workplace, we recommend these specific actions:

Do not eat, drink, or chew gum in the production area.

- Create or add to existing standard operating procedures that food and drink are not allowed in work areas.
- Post signs that tell employees food and drink are not allowed in work areas.

Ensure proper and consistent use of stepladders.

- Require employees to use a stepladder when they need to reach something. Make sure stepladders are easily available for them to use.
- Ensure that stepladders are tall enough for any employee so that they do not need to use the top step.
- Train employees on the proper use of stepladders. Tell them not to stand on the top of the ladder.

Use a hook on the wall to secure compressed air nozzles.

- Securing the nozzles for the compressed air will prevent them from possibly causing injury.

Create written standard operating procedures and post signs reminding employees what specific work areas and tasks require the use of personal protective equipment.

- Require employees wear safety glasses in the production areas and any time compressed air is used.
- Require employees wear protective footwear, such as steel-toed or composite-toed footwear or external safety toecaps, when there is a risk of foot injuries due to heavy rolling or falling objects.
- Ensure that employees know when they are working with materials that contain active pharmaceutical ingredients and that additional precautions may be necessary to reduce exposures.

Supporting Technical Information

Evaluation of Exposures to Dust and Noise at a Pharmaceutical Manufacturing Facility

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Section A: Workplace Information

Employee Information

The facility employed manufacturing and packaging employees and chemists. These employees all worked full time, Monday through Friday from 8 a.m. to 5 p.m., with the occasional night or weekend shift depending on production demands. Some employees were on compressed schedules, with every other Monday or Friday off. The facility also had a contract with a biomedical research institute that supplied contractors in the clinical manufacturing, clinical materials management, and biopharmaceutical laboratory sections. Government employees were represented by the American Federation of Government Employees (AFGE) labor union.

Process Description

Manufacturing

Employees in the manufacturing section made placebos for research. Manufacturing employees manually scooped powder into the blenders, comminutor (grinder), tablet press, and capsule fillers. Employees in this section used machines to blend, grind, or mill bulk powder to achieve desired properties. The powder was then taken to the tablet press, where it was pressed into tablets, or to the capsule filler, where it was dispensed into gelatin capsules.

During tablet pressing, a manufacturing employee lifted a 20, 30, or 40 kilogram container of bulk powder onto a table next to a Korsch tablet press. The employee then climbed a stepladder, reached down to fill their scoop with powder, then stepped up the ladder to load the hopper on top of the machine. The machine pressed the powder into tablets. During this process, the employee occasionally scraped down the powder on the sides of the hopper. The tablets were run through a deduster, which removed dust from the tablets, and dispensed into a container lined with a plastic bag.

Depending on the clinical trial, employees also filled capsules with powdered active pharmaceutical ingredients (APIs), over-encapsulated (place inside another capsule) tablets or capsules containing APIs, or coated tablets and capsules with polymeric materials. These processes were done to ensure that the drug and placebo look as identical as possible.

During capsule filling, a manufacturing employee scooped empty capsules into the capsule-separator's hopper. The capsule separator then separated the tops from the bottoms of the capsules using a vacuum system. The bottoms of the capsules were taken to a nearby table where employees hand-filled each capsule with a tablet. Next, employees scooped and tamped down powder until the capsule's target weight was achieved. Lastly, the tops and bottoms of the capsules were put back together in the capsule joiner. Finished capsules were dispensed into a container lined with a plastic bag.

Packaging

Employees in the packaging section used automated machines to dispense tablets and capsules into bottles or blister cards. If tablets were dusty, a vacuum could be attached to the bottle packaging machine to collect dust. Employees noted during our virtual walkthrough that the vacuum produced

more noise than the equipment itself. An automated machine also placed caps on bottles. Employees noted that this process produced noise due to the use of compressed air to shake down lids from the hopper. The blister card machine also used compressed air, and noise levels varied with its use. Employees noted that the highest noise levels occurred when a blister card was rejected by the machine using compressed air.

Biopharmaceutical Laboratory

Chemists in the biopharmaceutical laboratory section performed quality control and quality assurance checks.

Section B: Methods, Results, and Discussion

The objectives of this evaluation were to observe work processes, practices, and conditions; measure dust concentrations during processes or tasks producing dust; and measure employee exposures to noise during pharmaceutical manufacturing and packaging.

Methods: Exposure Assessment

Particulates

DustTrak Monitors

We measured particulates using DustTrak™ DRX 8533 aerosol monitors (TSI, Inc.) during tablet bottling, bottling-machine cleaning, tablet pressing, and capsule filling. Three monitors were used in the bottling room: one on a table next to the sealer, torquer, and labeler; one near the desiccant inserter and cotton inserter; and one near the supply hopper. Three monitors were used in the tablet press room: one on top of the tablet press, one in front of the deduster, and one on a cart in front of the tablet press. Two monitors were used in the capsule filling room: one on a cart in front of the door and one on the table where the capsule filling was taking place.

All monitors were set to log particle mass concentrations every 60 seconds in different size groups: particulate matter (PM) smaller than 1 micron (μm) (PM_1); PM smaller than 2.5 μm ($PM_{2.5}$); respirable (less than 4 μm); PM smaller than 10 μm (PM_{10}); and total PM (less than 100 μm). The data output was expressed as the mass concentration of particles per cubic meter (mg/m^3) of the sampled air. The lower instrument range was less than 0.001 mg/m^3.

Condensation Particle Counters

We also measured particulates using TSI® Model 3007 handheld condensation particle counters (CPCs) during tablet bottling, bottling-machine cleaning, tablet pressing, and capsule filling. Three CPCs were used in the bottling room: one on a table next to the sealer, torquer, and labeler; one near the desiccant inserter and cotton inserter; and one near the supply hopper. Three CPCs were used in the tablet press room: one held in the breathing zone of the worker who scooped powder into the hopper, one in front of the deduster, and one on a cart in front of the tablet press. Two CPCs were used in the capsule filling room: one on a cart in front of the door and one on the table where the capsule filling was taking place. All CPCs were set to log particle number concentrations every second in the size range of 0.01 to >1 μm. The data output is expressed as the total number of particles per cubic centimeter (p/cc) of the sampled air. The detectable concentration for the CPC ranges from 0 to 100,000 p/cc.

Noise

We measured time-weighted average (TWA) personal noise exposures of five production area employees and one biopharmaceutical lab employee over a 1-day period. We used Larson Davis Spartan™ Model 730 integrating noise dosimeters equipped with 0.25-inch random incidence microphones (Model 375A03). The dosimeters recorded and data-logged 1-second averaged noise levels for the duration of the measurement period.

We attached the dosimeter and microphone to the outside of employees' clothing, midway between the neck and the edge of their shoulder. The microphone was covered with a windscreen to reduce artifact

noise caused by air movement or accidental bumping. The dosimeters simultaneously collected noise data using three different settings to allow comparison of noise measurement results with three different noise exposure limits: the NIOSH recommended exposure limit (REL), the OSHA permissible exposure limit (PEL), and the OSHA action level (AL).

We used a Larson Davis Model 831 Type 1 integrating sound level meter and frequency analyzer equipped with a 0.5-inch random incidence microphone for sound level measurements. We measured sound levels at various points in the production process, including during bottling, blister carding, bottling-machine cleaning, vacuuming, and over-encapsulation of tablets. We also took sound level measurements in the air compressor room and during the release of air pressure in the outside liquid nitrogen tank. The instrument integrated sound levels using linear averaging at 1-second time history intervals. During measurements, the sound level meter was hand held at a height of approximately 5 feet above floor or ground level. Most measurements were taken within 3–6 feet of employees. Measurement durations ranged from 5–141 seconds, with a median duration of 49 seconds.

The dosimeters and sound level meters were calibrated before and after each day of measurements according to the manufacturer's instructions. Following measurements, the noise measurement data stored on the instruments were downloaded, exported, and analyzed using Larson Davis G4® software and Microsoft® Excel® for Office 365®.

Results: Exposure Assessment

Particulates

DustTrak Monitors

Particle mass concentrations were low during the bottling of tablets, across all size ranges (see Table C1). Respirable dust ranged from less than 0.001 to 0.001 mg/m^3 near the sealer, torquer, and labeler; 0.001 to 0.007 mg/m^3 near the desiccant inserter and cotton inserter; and less than 0.001 to 0.002 mg/m^3 near the supply hopper.

During bottling-room cleaning, particle mass concentrations were low across all size ranges. Respirable dust ranged from less than 0.001 to 0.009 mg/m^3 near the sealer, torquer, and labeler; 0.002 to 0.021 mg/m^3 near the desiccant inserter and cotton inserter; and less than 0.001 to 0.010 mg/m^3 near the supply hopper.

During tablet pressing, respirable dust ranged from 0.002 to 5.36 mg/m^3 near the top of the tablet press where powder was scooped into the hopper; 0.004 to 1.78 mg/m^3 in front of the deduster; and 0.010 to 1.51 mg/m^3 on a cart placed in front of the tablet press. Figure B1 shows the continuous concentration of respirable dust during tablet pressing. Ambient respirable dust concentrations in the room were measured from 2:45 p.m. to when the employee first started hand scooping powder into the hopper. The concentration of respirable dust measured on top of the tablet press increased after the employee hand scooped powder. For example, an employee hand scooped powder around 2:53 p.m. During this event, the concentration of respirable dust increased within a minute, and then abruptly fell. We found a similar pattern when an employee hand scooped powder around 2:59 p.m. After the peaks, the concentration of respirable dust in the room declined quickly to background levels.

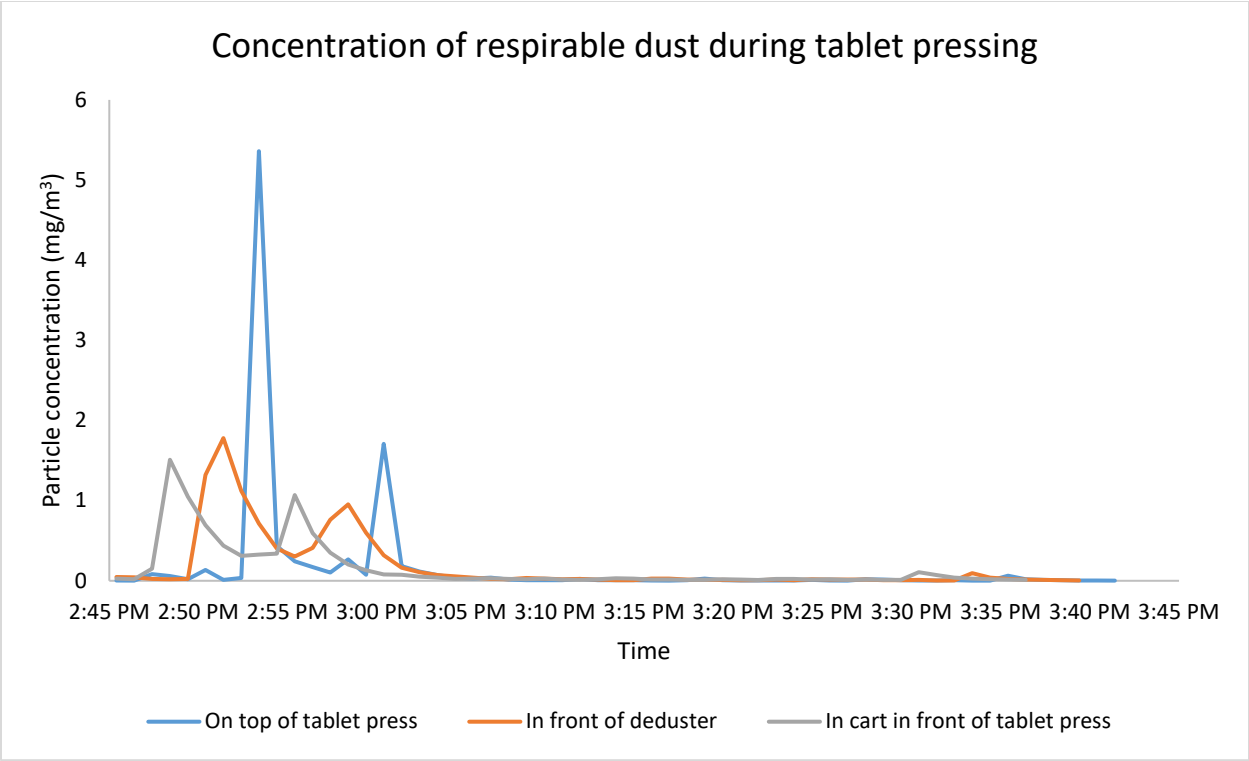

Figure B1. Concentration of respirable dust during tablet pressing. The concentration of respirable dust measured on top of the tablet press increased after the employee hand scooped powder. After the peaks, the concentration of respirable dust in the room declined quickly to background levels.

During capsule filling, respirable dust ranged from 0.003 to 0.056 mg/m^3 on a cart placed in front of the door, and less than 0.001 to 0.279 mg/m^3 on the table near the manual capsule-filling process.

Condensation Particle Counters

During the bottling of tablets, particle number concentrations ranged from 0 to 18 p/cc near the sealer, torquer, and labeler; 0 to 9 p/cc near the desiccant inserter and cotton inserter; and 0 to 46 p/cc near the supply hopper (see Table C2).

During the cleaning of the bottling room, particle number concentrations ranged from 0 to 56 p/cc near the sealer, torquer, and labeler; 0 to 61 p/cc near the desiccant inserter and cotton inserter; and 0 to 1,300 p/cc near the supply hopper.

During tablet pressing, particle number concentrations ranged from 1 to 120 p/cc in the breathing zone of the worker who scooped powder into the hopper, 0 to 270 p/cc in front of the deduster, and 0 to 200 p/cc on a cart placed in front of the tablet press.

During capsule filling, particle number concentrations ranged from 0 to 18 p/cc on a cart placed in front of the door, and 1 to 5 p/cc on the table near the manual capsule-filling process.

Noise

Sound level measurement results are provided in Table C3 in Section C. Sound levels in most of the production areas were below 85 decibels, A-weighted (dBA). However sound levels during use of

compressed air typically exceeded 95 dBA and were sometimes greater than 100 dBA for short periods of time. Sound levels were above 90 dBA when draining water from the compressors in the compressor room and during use of the vacuum at the Korsch tablet press. Sound levels in the bottling room near the vibrating bowl, which oriented bottle caps, and at the "caps call" area at the back of the chuck capper were 88–89 dBA. The noise at the vibrating bowl was caused when the bowl was mechanically vibrated and that vibration transmitted to the metal framework. Noise at the chuck capper was due to compressed air from the equipment blowing on the underside of the bottle cap.

The highest sound levels we measured at the facility occurred at the large outdoor nitrogen tank when an employee released pressurized nitrogen gas during initial "bleeding" of the tank. Near the tank, sound levels averaged 112 dBA and ranged from 110 dBA to 115 dBA. After the initial bleeding of the tank, which usually took less than 20 seconds, the employee moved about 30 feet away from the tank where sound levels were about 85 dBA.

Employees' full-shift noise exposures, shown in Table C4 in Section C, were below OSHA and NIOSH noise exposure limits. Employees in the bottling room had the highest TWA noise exposures, ranging from 82.1 to 82.8 dBA, based on NIOSH noise measurement criteria. Figure B2 shows one of the bottling employees' time-history noise exposures during the work shift. During active bottling operations, noise exposures were generally 70 to 90 dBA. When compressed air was used for cleaning and drying, noise exposures reached or exceeded 100 dBA for short periods.

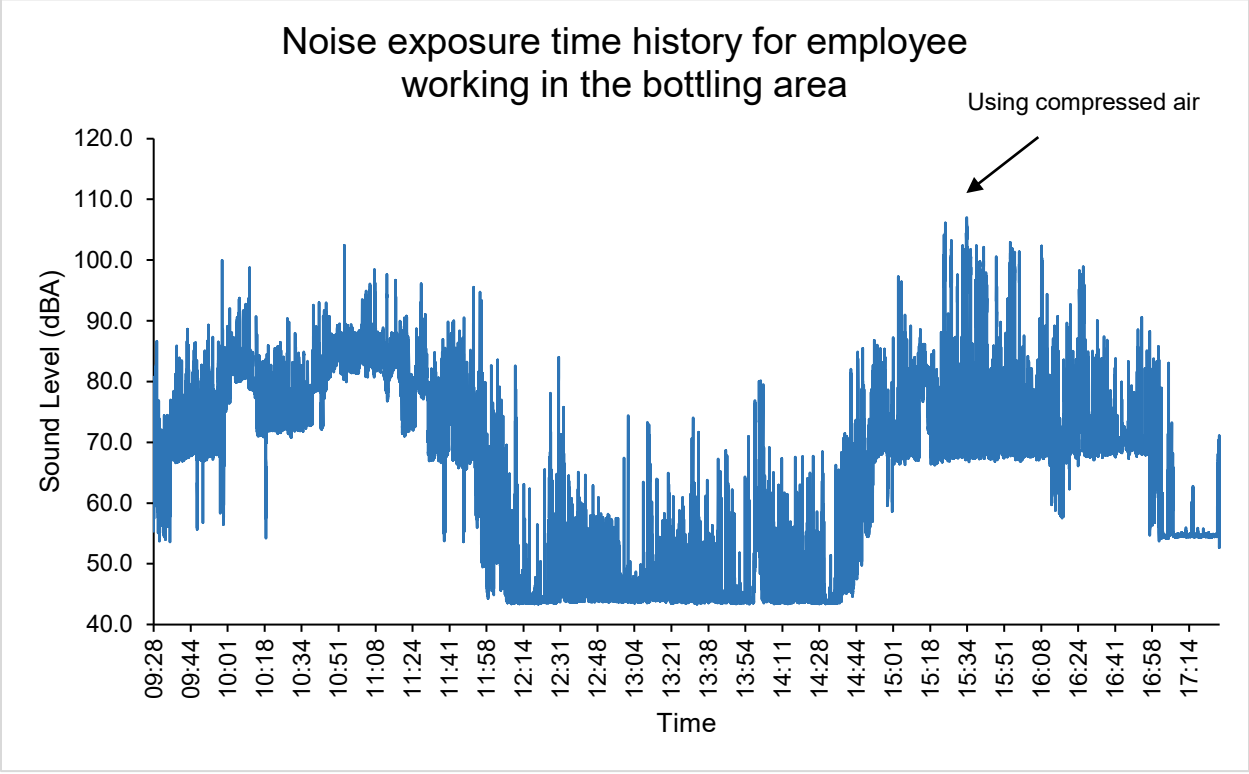

Figure B2. Noise exposure time history for employee working in the bottling area. During active bottling operations, noise exposures were generally 70 to 90 dBA. When compressed air was used for cleaning and drying, noise exposures reached or exceeded 100 dBA for short periods.

Discussion

Our results indicated that particulate levels were lowest during tablet bottling and bottling-room cleaning. Particulate levels were slightly greater during capsule filling. During that time, peaks in respirable dust concentrations occurred when employees hand scooped powder to fill the capsules. The highest particulate levels we measured occurred during tablet pressing activities, particularly when employees hand scooped and dumped powder into the hopper of the tablet press or scraped down the powder on the sides of the hopper.

The OSHA PEL for airborne total dust is 15 milligrams per cubic meter (mg/m^3) over an 8-hour TWA. Total dust means particles of various sizes and composition. This PEL is for particulates not otherwise regulated, including nuisance dust or inert dust. For dust containing active pharmaceutical ingredients, this PEL would not be applicable. Particles larger than 100 μm in diameter may be too big to enter the deepest areas of the lungs but can enter the nose, mouth, and upper airways during breathing. Particles smaller than 4 μm in diameter are respirable and can penetrate deeply into the lower respiratory system [ACGIH 2023]. Fine particles (less than 2.5 μm in diameter) and ultrafine particles (less than 0.1 μm in diameter) are primarily deposited in the small airways and alveoli [EPA 2023]. Ultrafine particles are small enough to pass through the alveoli into the bloodstream [American Lung Association 2023]. Acute and chronic exposure to respirable particles have been linked with adverse health effects, including cardiovascular disease, respiratory disease, developmental and reproductive effects, and lung cancer [EPA 2023].

The OSHA PEL for respirable dust is 5 mg/m^3 over an 8-hour TWA. The American Conference of Governmental Industrial Hygienists (ACGIH®) recommends that airborne concentrations of respirable dust be kept below 3 mg/m^3 [ACGIH 2023]. None of the average particle mass concentrations from the activities measured exceeded the full-shift OSHA PEL for total or respirable dust or ACGIH guidelines for respirable dust. However, particle concentrations did reach these levels for short periods during tablet pressing when the employee hand scooped powder into the hopper. In addition, the amount of time employees might be exposed to these higher levels is limited to the time spent at the task. Based on the work activities and the relatively limited amount of time spent scooping powders on typical workdays, we would not expect exposure to reach OELs. It is important to note that these measurements were area samples, and so cannot be directly compared with OELs, which are for personal exposures. However, implementing strategies to reduce dust levels can help minimize employee dust exposures.

None of the employees TWA noise exposures exceeded noise exposure limits. During production activities in the bottling room, noise exposures were above 90 dBA at times; however, the total time above 90 dBA, based on noise dosimeter time history data, was less than 20 minutes on the day of monitoring. If the total time at 90 dBA was 150 minutes, TWA noise exposures would be at the NIOSH REL [NIOSH 1998].

When employees used compressed air to clean and dry bottling-room equipment, the noise levels were sometimes at or above 100 dBA for brief periods. Noise dosimeter time history data revealed that the total time above 100 dBA during the shift was 0.75 to 1.3 minutes. If the amount of time spent doing bottling activities and using compressed air increased, noise exposures could potentially reach noise

exposure limits. TWA noise exposures would exceed the NIOSH REL if the total time at 100 dBA was 15 minutes or more. We recommend continuing to use hearing protection during activities that generate sound levels above 85 dBA. Although initial bleeding of the large outdoor nitrogen tank, where sound levels ranged 110 to 115 dBA, usually took less than 30 seconds, we recommend use of both ear plugs and earmuffs when the employee is at the tank.

One of the contributors to noise exposures in the bottling room was sound generated by compressed air used by some of the production equipment, as well as by workers to dry equipment following cleaning. Air exiting compressed air nozzles, such as open tube nozzles or nozzles with internal threading, generates air turbulence and high sound levels. These nozzles also tend to use more compressed air than may be necessary and can therefore be more costly. Some manufacturers of engineered compressed air nozzles have shown that open tube nozzles generate up to 10 dB more noise than properly engineered nozzles. In contrast, efficient air nozzles complete the required task, generate less turbulence, produce less noise, and reduce compressed air consumption by 30% to 60%, resulting in cost savings [Saidur et al. 2010]. Sound levels in the bottling room and other areas where compressed air is used could potentially be reduced by installing and using compressed air nozzles designed to produce less noise.

Limitations

Our exposure assessment documented exposures and conditions in the locations evaluated and on the days which the evaluation occurred. These results may not be representative of conditions during other days.

Conclusions

None of the average particle mass concentrations from the activities measured exceeded the OSHA PEL for total or respirable dust or ACGIH guidelines for respirable dust. However, particle concentrations reached these levels for short periods of time during tablet pressing when the employee hand scooped powder into the hopper. We recommend reducing airborne dust exposure as much as practicable by reducing or eliminating hand scooping of powder, reducing powder transport distance from containers to hoppers, eliminating use of compressed air to blow dust and powder off clothing, and minimizing use of compressed air to clean equipment.

Employees in the bottling room had the highest full-shift noise exposures. However, noise exposures did not exceed noise exposure limits. If the amount of time spent doing bottling room activities and using compressed air increased, noise exposures could potentially reach noise exposure limits. Noise in the bottling room and other areas where compressed air is used could potentially be reduced by using compressed air nozzles designed to produce less noise. We recommend continuing to use hearing protection during activities that generate sound levels above 85 dBA.

Section C: Tables

Table C1. Particle mass concentration results for four processes (mg/m^3) using DustTrak™ DRX 8533 aerosol monitors. Lower instrument range (LIR) was less than 0.001 mg/m^3

Location	Particle size				
	PM_1	$PM_{2.5}$	Respirable	PM_{10}	Total
Bottling of tablets					
Near sealer, torquer, and labeler					
Average	< LIR	< LIR	< LIR	0.001	0.014
Minimum	< LIR	< LIR	< LIR	< LIR	< LIR
Maximum	0.001	0.001	0.001	0.002	0.039
Near desiccant inserter and cotton inserter					
Average	0.003	0.003	0.003	0.004	0.008
Minimum	0.001	0.001	0.001	0.001	0.002
Maximum	0.006	0.006	0.007	0.008	0.028
Near supply hopper					
Average	< LIR	< LIR	< LIR	0.001	0.002
Minimum	< LIR	< LIR	< LIR	< LIR	< LIR
Maximum	0.002	0.002	0.002	0.003	0.009
Cleaning of bottling room					
Near sealer, torquer, and labeler					
Average	< LIR	< LIR	< LIR	0.001	0.017
Minimum	< LIR	< LIR	< LIR	< LIR	< LIR
Maximum	0.008	0.009	0.009	0.020	0.337
Near desiccant inserter and cotton inserter					
Average	0.004	0.005	0.005	0.005	0.009
Minimum	0.002	0.002	0.002	0.002	0.002
Maximum	0.020	0.020	0.021	0.027	0.059
Near supply hopper					
Average	0.001	0.001	0.001	0.002	0.004
Minimum	< LIR	< LIR	< LIR	< LIR	< LIR
Maximum	0.010	0.010	0.010	0.013	0.025

Table C1 (continued). Particle mass concentration results for four processes (mg/m^3) using DustTrak™ DRX 8533 aerosol monitors. Lower instrument range (LIR) was less than 0.001 mg/m^3

Location	Particle size				
	PM_1	$PM_{2.5}$	Respirable	PM_{10}	Total
Tablet pressing					
On top of tablet press					
Average	0.166	0.166	0.167	0.224	5.59
Minimum	0.002	0.002	0.002	0.003	0.111
Maximum	5.33	5.33	5.36	6.87	117
In front of deduster					
Average	0.178	0.179	0.180	0.274	0.710
Minimum	0.004	0.004	0.004	0.007	0.021
Maximum	1.77	1.77	1.78	2.62	6.76
On cart in front of tablet press					
Average	0.157	0.157	0.159	0.250	0.893
Minimum	0.010	0.010	0.010	0.013	0.039
Maximum	1.50	1.50	1.51	2.29	7.99
Capsule filling					
On cart in front of door					
Average	0.009	0.009	0.009	0.015	0.033
Minimum	0.003	0.003	0.003	0.003	0.003
Maximum	0.055	0.055	0.056	0.123	0.282
On table near capsule filling					
Average	0.021	0.021	0.021	0.057	1.12
Minimum	< LIR	< LIR	< LIR	< LIR	0.004
Maximum	0.275	0.276	0.279	0.537	12

Table C2. Particle number concentration results for four processes (p/cc) using TSI® Model 3007 handheld condensation particle counters (CPCs)

Location	Particle number concentration
Bottling of tablets	
Near sealer, torquer, and labeler	
Average	1.2
Minimum	0.0
Maximum	18
Near desiccant inserter and cotton inserter	
Average	2.3
Minimum	0.0
Maximum	9.0
Near supply hopper	
Average	1.9
Minimum	0.0
Maximum	46
Cleaning of bottling room	
Near sealer, torquer, and labeler	
Average	5.3
Minimum	0.0
Maximum	56
Near desiccant inserter and cotton inserter	
Average	9.2
Minimum	0.0
Maximum	61
Near supply hopper	
Average	17
Minimum	0.0
Maximum	1,300

Table C2 (continued). Particle number concentration results for four processes (p/cc) using TSI® Model 3007 handheld condensation particle counters (CPCs)

Location	Particle number concentration
Tablet pressing	
Breathing zone of powder scooper	
Average	24
Minimum	1.0
Maximum	120
In front of deduster	
Average	33
Minimum	0.0
Maximum	270
On cart in front of tablet press	
Average	36
Minimum	0.0
Maximum	200
Capsule filling	
On cart in front of door	
Average	1.0
Minimum	0.0
Maximum	18
On table near capsule filling	
Average	2.1
Minimum	1.0
Maximum	5.0

Table C3. Integrated sound level measurements using a Larson Davis Model 831 Type 1 integrating sound level meter and frequency analyzer equipped with a 0.5-inch random incidence microphone

Location and measurement description	Sound level (dBA)
Bottling room; station 1 (placing bottles); CMMS/0067	83.9
Bottling room; station 2 (left of bottle fill); CMMS/0068	84.5
Bottling room; station 3 (clicking noise from actuator); CMMS 0069	83.9
Bottling room; station 4 (desiccant, not in use); CMMS 0070	84.9
Bottling room; station 5 (adding cotton); CMMS 0071	82.4
Bottling room; station 6 (chuck capper); CMMS 0072	83.1
Bottling room; pulling bottles for quarantine	83.2
Bottling room; near vibrating bowl that orients caps	88.0
Bottling room; background in room with conveyor the only equipment running	72.2
Bottling room; near "caps call" at back of chuck capper; compressed air blows on underside of cap	88.6
Uhlmann; background with equipment on but not running; some noise from ThermoScientific chiller	68.5
Uhlmann; on left side	81.2
Uhlmann; on right side near reject part (usually this doesn't run continuously)	85.3
Uhlmann; at central part	82.2
Compressor room; sound levels range 77–84 dBA across room	82.8
Compressor room; draining water	92.4
Bottling room; using compressed air to dry part; measurement on left side of employee	99.7
Bottling room; using compressed air to dry part; measurement on right side of employee	96.4
Bottling room; using compressed air to blow down equipment	92.8
Using Korsch XL 200 tablet press; background noise in room	70.6
Using Korsch XL 200 tablet press; dumping raw material in hopper on top of unit	82.5
Using Korsch XL 200 tablet press; 5 feet from Nilfisk T63 vacuum	84.7
Using Korsch XL 200 tablet press; area along left side of Korsch unit	85.4
Using Korsch XL 200 tablet press; about 7 feet from front of Korsch unit	82.6
At Korsch XL 200 tablet press; using compressed air to simulate cleaning	99.7
At Korsch XL 200 tablet press; using Nilfisk T63 vacuum; vacuum hooked up to Korsch	84.5
At Korsch XL 200 tablet press; using Nilfisk T63 vacuum to clean Korsch	91.1
Over-encapsulation room; using compressed air (Guardair nozzle)	104.6
Over-encapsulation room; using small Nilfisk vacuum	84.0
Over-encapsulation room; using Nilfisk CFM S3 vacuum; simulated run; CMS 0030; lowest setting	76.7
Over-encapsulation room; using Nilfisk CFM S3 vacuum; highest setting; simulated run; CMS 0030	83.0

Table C3 (continued). Integrated sound level measurements using a Larson Davis Model 831 Type 1 integrating sound level meter and frequency analyzer equipped with a 0.5-inch random incidence microphone

Location and measurement description	Sound level (dBA)
Coating room; HET air filter used for O'Hara coating equipment	82.8
Coating room; HET air filter used for O'Hara coating equipment	81.0
Coating room; near employee station at O'Hara	82.6
Coating room; near work area at O'Hara	82.3
Coating room; using Nilfisk CFM S3 vacuum at highest setting	83.3
Capsule fill; placing capsule in metal ring	80.2
Belco machine; 3 cycles	67.3
Belco machine; 3 cycles, holding box over exhaust on side of machine to simulate partial enclosure	63.6
Initial bleed of nitrogen tank (near tank)	112.3
Bleeding nitrogen tank (30 feet from tank near worker observing operation)	85.8
Bleeding nitrogen tank (120 feet from tank at picnic table)	79.2

Table C4. Employees full-shift noise exposure measurement results in decibel, A-weighted (dBA), using Larson Davis Spartan™ Model 730 integrating noise dosimeters equipped with 0.25-inch random incidence microphones (Model 375A03)

Work area	Result using NIOSH REL criterion*	Result using OSHA AL criterion*	Result using OSHA PEL criterion†
Production (bottling room)	82.1	74.8	69.6
Production (bottling room)	82.8	78.0	82.8
Production (multiple areas)	77.5	70.5	61.5
Production (annex area in morning / tablet press in afternoon)	79.1	73.6	59.8
Laboratory	63.6	46.1	41.2
Systems engineering (worked throughout facility)	81.5	76.1	68.5
Noise exposure limits (8-hour work shift)	85	85	90

*The criteria for calculating the NIOSH recommended exposure level (REL) and OSHA action level (AL) includes all noise exposure greater than or equal to 80 dBA.

†The criteria for calculating the OSHA permissible exposure limit (PEL) includes all noise exposure greater than or equal to 90 dBA.

Section D: Occupational Exposure Limits

NIOSH investigators refer to mandatory (legally enforceable) and recommended OELs for chemical, physical, and biological agents when evaluating workplace hazards. OELs have been developed by federal agencies and safety and health organizations to prevent adverse health effects from workplace exposures. Generally, OELs suggest levels of exposure that most employees may be exposed to for up to 10 hours per day, 40 hours per week, for a working lifetime, without experiencing adverse health effects. However, not all employees will be protected if their exposures are maintained below these levels. Some may have adverse health effects because of individual susceptibility, a preexisting medical condition, or a hypersensitivity (allergy). In addition, some hazardous substances act in combination with other exposures, with the general environment, or with medications or the personal habits of the employee to produce adverse health effects. Most OELs address airborne exposures, but some substances can be absorbed directly through the skin and mucous membranes.

Most OELs are expressed as a TWA exposure. A TWA refers to the average exposure during a normal 8- to 10-hour workday. Some chemical substances and physical agents have recommended short-term exposure limits ceiling values. Unless otherwise noted, the short-term exposure limit is a 15-minute TWA exposure. It should not be exceeded at any time during a workday. The ceiling limit should not be exceeded at any time.

In the United States, OELs have been established by federal agencies, professional organizations, state and local governments, and other entities. Some OELs are legally enforceable limits; others are recommendations.

- The U.S. Department of Labor OSHA permissible exposure limits (29 CFR 1910 [general industry]; 29 CFR 1926 [construction industry]; and 29 CFR 1917 [maritime industry]) are legal limits. These limits are enforceable in workplaces covered under the Occupational Safety and Health Act of 1970.
- NIOSH RELs are recommendations based on a critical review of the scientific and technical information and the adequacy of methods to identify and control the hazard. NIOSH RELs are published in the NIOSH Pocket Guide to Chemical Hazards [NIOSH 2007]. NIOSH also recommends risk management practices (e.g., engineering controls, safe work practices, employee education/training, personal protective equipment, and exposure and medical monitoring) to minimize the risk of exposure and adverse health effects.
- Another set of OELs commonly used and cited in the United States is the ACGIH TLVs. The TLVs are developed by committee members of this professional organization from a review of the published, peer-reviewed literature. TLVs are not consensus standards. They are considered voluntary exposure guidelines for use by industrial hygienists and others trained in this discipline "to assist in the control of health hazards" [ACGIH 2023].

Outside the United States, OELs have been established by various agencies and organizations and include legal and recommended limits. The Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety and Health of the German Social Accident

Insurance) maintains a database of international OELs from European Union member states, Canada (Québec), Japan, Switzerland, and the United States. The database, available at http://www.dguv.de/ifa/GESTIS/GESTIS-Internationale-Grenzwerte-für-chemische-Substanzen-limit-values-for-chemical-agents/index-2.jsp, contains international limits for more than 2,000 hazardous substances and is updated periodically.

OSHA requires an employer to furnish employees a place of employment free from recognized hazards that cause or are likely to cause death or serious physical harm (Occupational Safety and Health Act of 1970; Public Law 91-596, sec. 5[a][1]). This is true in the absence of a specific OEL. It also is important to keep in mind that OELs may not reflect current health-based information.

When multiple OELs exist for a substance or agent, NIOSH investigators generally encourage employers to use the lowest OEL when making risk assessment and risk management decisions.

Noise

Noise-induced hearing loss (NIHL) is an irreversible condition that progresses with noise exposure. NIHL is caused by damage to the nerve cells of the inner ear and, unlike some other types of hearing disorders, cannot be treated medically [AIHA 2022]. Approximately 25% of U.S. workers have been exposed to hazardous noise [Kerns et al. 2018] and more than 22 million U.S. workers are estimated to be exposed to workplace noise levels above 85 dBA [Tak et al. 2009]. NIOSH estimates that workers exposed to an average daily noise level of 85 dBA over a 40-year working lifetime have an 8% excess risk of material hearing impairment. This excess risk increases to 25% for an average daily noise exposure of 90 dBA [NIOSH 1998]. NIOSH defines material hearing impairment as an average of the HTLs for both ears that exceeds 25 decibels (dB) at frequencies of 1 kilohertz (kHz), 2 kHz, 3 kHz, and 4 kHz.

Although hearing ability commonly declines with age, exposure to excessive noise can increase the rate of hearing loss. In most cases, NIHL develops slowly from repeated exposure to noise over time, but the progression of hearing loss is typically the greatest during the first several years of noise exposure [Rosler 1994]. NIHL can result from short duration exposures to high noise levels or even from a single exposure to an impulsive noise or a continuous noise, depending on the intensity of the noise and the individual's susceptibility to NIHL [AIHA 2022]. Noise exposed workers can develop substantial NIHL before it is clearly recognized. Even mild hearing losses can impair one's ability to understand speech and hear many important sounds. In addition, some people with NIHL also develop tinnitus. Tinnitus is a condition in which a person perceives hearing sound in one or both ears, but no external sound is present. Persons with tinnitus often describe hearing ringing, hissing, buzzing, whistling, clicking, or chirping like crickets. Tinnitus can be intermittent or continuous and the perceived volume can range from soft to loud. Currently, no cure for tinnitus exists.

Noise measurements are usually reported as dBA. A-weighting is used because it approximates the "equal loudness perception characteristics of human hearing for pure tones relative to a reference of 40 dB at a frequency of 1 kHz" and is considered to provide a better estimation of hearing loss risk than using unweighted or other weighting measurements [Murphy et al. 2022]. The dB unit is dimensionless, and it represents the logarithmic ratio of the measured sound pressure level to an arbitrary reference

sound pressure of 20 micropascals, which is defined as the threshold of normal human hearing at a frequency of 1 kHz. Because the dB is logarithmic, an increase of 3 dB is a doubling of the sound energy, an increase of 10 dB is a 10-fold increase, and an increase of 20 dB is a 100-fold increase in sound energy. Noise exposures expressed in dB or dBA cannot be averaged using the arithmetic mean.

Workers exposed to noise should have baseline and yearly hearing tests (audiograms) to evaluate their hearing thresholds and determine whether their hearing has changed over time. Hearing testing should be done in a quiet location, such as an audiometric test booth, where background noise does not interfere with accurate measurement of hearing thresholds. In workplace hearing conservation programs, hearing thresholds must be measured at frequencies of 0.5 kHz, 1 kHz, 2 kHz, 3 kHz, 4 kHz, and 6 kHz. NIOSH also recommends testing be done at 8 kHz [NIOSH 1998].

The OSHA hearing conservation standard requires analysis of hearing changes from baseline hearing thresholds to determine if a standard threshold shift (STS) has occurred. OSHA defines an STS as a change in hearing threshold relative to the baseline hearing test of an average of 10 dB or more at 2 kHz, 3 kHz, and 4 kHz in either ear [29 CFR 1910.95]. If an STS occurs, the company must determine if the hearing loss also meets the requirements to be recorded on the OSHA Form 300 Log of Work-Related Injuries and Illnesses [29 CFR 1904.1]. In contrast to OSHA, NIOSH defines a significant threshold shift as an increase in the hearing threshold level of 15 dB or more, relative to the baseline audiogram, at any test frequency in either ear measured twice in succession [NIOSH 1998].

Hearing test results are often presented in an audiogram, which is a plot of an individual's hearing thresholds (*y*-axis) at each test frequency (*x*-axis). Hearing threshold levels (HTLs) are plotted such that fainter sounds are shown at the top of the *y*-axis, and more intense sounds are plotted below. Typical audiograms show HTLs from −10 or 0 dB to about 100 dB. Lower frequencies are plotted on the left side of the audiogram, and higher frequencies are plotted on the right. NIHL often manifests itself as a "notch" at 3 kHz, 4 kHz, or 6 kHz, depending on the frequency spectrum of the workplace noise and the anatomy of the individual's ear [Mirza et al. 2018; Osguthorpe and Klein 1991; Schlauch and Carney 2011; Suter 2002]. A notch in an individual with normal hearing may indicate early onset of NIHL. A notch is defined as the frequency where the HTL is preceded by an improvement of at least 10 dB at the previous test frequency and followed by an improvement of at least 5 dB at the next test frequency.

NIOSH has an REL for noise of 85 dBA as an 8-hour TWA. For calculating exposure limits, NIOSH uses a 3-dB time/intensity trading relationship, or exchange rate. Using this criterion, an employee can be exposed to 88 dBA for no more than 4 hours, 91 dBA for 2 hours, 94 dBA for 1 hour, 97 dBA for 0.5 hours, etc. Exposure to impulsive noise should never exceed a peak level of 140 dBA. For extended work shifts, NIOSH adjusts the REL to 84.5 dBA for a 9-hour shift, 84.0 dBA for a 10-hour shift, 83.6 dBA for an 11-hour shift, and 83.2 dBA for a 12-hour work shift. When noise exposures exceed the REL, NIOSH recommends the using hearing protection and implementing a hearing loss prevention program [NIOSH 1998].

The OSHA noise standard specifies a PEL of 90 dBA and an AL of 85 dBA, both as 8-hour TWAs. OSHA uses a less conservative 5-dB exchange rate for calculating the PEL and AL. Using the OSHA criterion, an employee may be exposed to noise levels of 95 dBA for no more than 4 hours, 100 dBA for 2 hours, 105 dBA for 1 hour, 110 dBA for 0.5 hours, etc. Exposure to impulsive noise must not

exceed 140 dB peak noise level. OSHA does not adjust the PEL for extended work shifts. However, the AL is adjusted to 84.1 dBA for a 9-hour shift, 83.4 dBA for a 10-hour shift, 82.7 dBA for an 11-hour shift, and 82.1 dBA for a 12-hour work shift. OSHA requires implementation of a hearing conservation program when noise exposures exceed the AL [29 CFR 1910.95].

An employee's daily noise dose, based on the duration and intensity of noise exposure, can be calculated according to the formula: Dose = $100 \times (C_1/T_1 + C_2/T_2 + ... + C_n/T_n)$, where C_n indicates the total time of exposure at a specific noise level, and T_n indicates the reference exposure duration for which noise at that level becomes hazardous. A noise dose greater than 100% exceeds the noise exposure limit.

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