United States of America
OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION
1120 20th Street, N.W., Ninth Floor
Washington, DC 20036-3457

SECRETARY OF LABOR, Complainant, v. METWEST, INC., Respondent.	OSHRC Docket No. 04-0594

APPEARANCES:

Mark J. Lerner, Attorney; Scott Glabman, Senior Appellate Attorney; Daniel J. Mick, Counsel for Regional Litigation; Joseph M. Woodward, Associate Solicitor; Howard M. Radzely, Solicitor; U.S. Department of Labor, Washington, DC
For the Complainant

Brent I. Clark, Esq. and James L. Curtis, Esq.; Seyfarth Shaw LLP, Chicago, IL
For the Respondent

DECISION

Before: THOMPSON, Chairman; and ROGERS, Commissioner.

BY THE COMMISSION:

STATEMENT OF THE CASE

MetWest, Inc. ("MetWest"), a wholly owned subsidiary of Quest Diagnostics, Inc. ("Quest"), operates patient service facilities nationwide where it employs phlebotomists to perform blood drawing services for hospitals, nursing homes, patient service centers, and clinics. On February 6, 2004, the Occupational Safety and Health Administration ("OSHA") began an inspection of a MetWest facility in Denver, Colorado. As a result of the inspection, OSHA issued MetWest a single-item serious citation under the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-678, alleging a violation of 29 C.F.R. § 1910.1030(d)(2)(vii)(A), a

provision of the Bloodborne Pathogen ("BBP") Standard that prohibits the removal of contaminated needles.[1]

MetWest contested the citation and a hearing was held before Administrative Law Judge Sidney J. Goldstein. The judge affirmed the citation as alleged and assessed the proposed penalty of $1,875. MetWest timely petitioned for review of the judge's decision, and Chairman Thompson directed the case for review. For the following reasons, we affirm the judge.[2]

ISSUES

In the citation, the Secretary alleges that MetWest violated § 1910.1030(d)(2)(vii)(A), which prohibits the removal of contaminated needles absent a showing of infeasibility or medical necessity, by allowing employees at its Denver facility to remove contaminated needles from reusable blood tube holders equipped with a push-button-needle-release mechanism. The judge concluded that "[t]he plain language of § 1910.1030(d)(2)(vii) prohibits," and has been interpreted by the Secretary since its promulgation in 1991 to "prohibit[,] the removal of contaminated needles unless no feasible alternative is available." Absent any showing by MetWest of infeasibility or medical necessity, and based on evidence showing that single-use blood tube holders—which do not require removal of the contaminated needle—have become readily available, the judge affirmed the violation.

The primary issue on review is whether the BBP Standard prohibits the cited conduct. Also at issue is the judge's reliance on testimony from one of the Secretary's witnesses and his granting of the Secretary's motion to amend the citation.[3]

FINDINGS OF FACT

The relevant facts in this case are not in dispute. At MetWest's Denver facility, two of its phlebotomists routinely collect patient blood samples using a reusable blood tube holder, known as the BD Pronto Quick Release Holder ("Pronto"), which is fitted with both a blood tube and a

[1] Section 1910.1030(d)(2)(vii)(A) states that "[c]ontaminated needles and other contaminated sharps shall not be bent, recapped, or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure."

[2] We deny MetWest's request for oral argument, as the record and briefs are sufficient to decide the case. *See AAA Delivery Servs., Inc.*, 21 BNA OSHC 1219, 1221 n.4, 2005 CCH OSHD ¶ 32,796, p. 52,449 n.4 (No. 02-0923, 2005).

[3] We do not address the "greater hazard defense" delineated in the Commission's briefing notice, as MetWest disclaimed any intent of asserting the defense either before the judge or on review.

double-ended needle. Since the Pronto blood tube holder is reusable, the phlebotomists routinely remove the double-ended needle from the holder by depressing a push-button-needle-release mechanism with one finger each time after they draw blood. The phlebotomists can thus retain the reusable blood tube holder for additional drawings of blood.

As MetWest acknowledges, when the BBP Standard was promulgated in 1991, reusable blood tube holders were the only type of blood tube holder readily available and had been the standard blood tube holder for nearly thirty years. By the time OSHA inspected MetWest's facility thirteen years later in 2004, single-use blood tube holders had been developed and made readily available. Many medical facilities, including some of Quest's own California facilities, currently use single-use blood tube holders.

I. MERITS OF THE CITATION

MetWest contends that § 1910.1030(d)(2)(vii)(A) prohibits two-handed needle removal but permits the type of one-handed needle removal employed by its phlebotomists.[4] According to MetWest, the Secretary's interpretation of the standard to prohibit the removal of contaminated needles from a blood tube holder by any means, including the Pronto's one-handed push-button-needle-release mechanism, is contrary to the legislative intent embodied in the BBP Standard's preamble and would illogically prohibit the removal of needles from patients' arms, as well as filled blood tubes. MetWest claims the Secretary has provided varied and inconsistent interpretations of the cited standard, initially permitting one-handed needle removal from reusable blood tube holders then later imposing a prohibition on this practice.

For the following reasons, we conclude that the BBP Standard, its legislative history and preamble to the final rule, and the Secretary's enforcement practice, support the judge's

[4] MetWest also claims the judge erred in finding that its employees were exposed to a needlestick hazard. However, the needle-removal provision of the BBP Standard is premised on the Secretary's explicit finding that "[n]eedlesticks are a very efficient means of transmitting bloodborne diseases" and her conclusion that "recapping or removal [of contaminated needles] should not be acceptable as a general practice. . . ." Occupational Exposure to Bloodborne Pathogens, 56 Fed. Reg. 64,004, 64,117-18 (Dec. 6, 1991) (codified at 29 C.F.R. § 1910.1030). Thus, exposure is established here by the undisputed fact that MetWest's employees removed contaminated needles from the reusable blood tube holders. *See Austin Bridge Co.*, 7 BNA OSHC 1761, 1765-66, 1979 CCH OSHD ¶ 23,935, p. 29,021 (No. 76-93, 1979) (stating that if a standard is predicated on the existence of a hazard, "the Secretary is not required to prove that noncompliance with [the] standard creates a hazard in order to establish a violation").

determination that the cited provision plainly prohibits MetWest's practice of removing contaminated needles from reusable blood tube holders.

PRINCIPLES OF LAW

Section 1910.1030(d)(2)(vii) of the BBP Standard states that "[c]ontaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B)" of this section. 29 C.F.R. § 1910.1030(d)(2)(vii). These two paragraphs provide the following exceptions:

> (A) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.
>
> (B) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

29 C.F.R. § 1910.1030(d)(2)(vii)(A)-(B).

As part of her burden of proof, the Secretary must show the employer failed to comply with the cited standard. *Atlantic Battery Co.*, 16 BNA OSHC 2131, 2138, 1993-95 CCH OSHD ¶ 30,636, p. 42,452 (No. 90-147, 1994). In construing the standard to determine its applicability, "the Commission and the courts consider (1) the language and structure of the specific statutory provision or regulation as well as of the regulatory framework or statute as a whole; (2) the legislative history; and, then, only if the drafter's intent remains unclear, (3) the reasonableness of an agency's interpretation." *Arcadian Corp.*, 17 BNA OSHC 1345, 1346, 1995-97 CCH OSHD ¶ 30,856, p. 42,916 (No. 93-3270, 1995) (citations omitted), *aff'd*, 110 F.3d 1192 (5th Cir. 1997).

ANALYSIS

We find that the language of § 1910.1030(d)(2)(vii)(A) plainly prohibits all contaminated needle removal except where the employer can demonstrate infeasibility or medical necessity. *E.g., Caminetti v. United States*, 242 U.S. 470, 485 (1917) (noting that statutory language is to be construed according to its plain meaning). This reading of the provision is underscored by the BBP Standard's legislative history, as well as the preamble to the final rule, which reiterates that the cited provision "requires that contaminated needles and other contaminated sharps shall not be bent, recapped, or resheathed except as noted in [paragraphs (d)(2)(vii)(A) and (B)] . . . ." Occupational Exposure to Bloodborne Pathogens ("BBP Final Rule"), 56 Fed. Reg. 64,004, 64,118 (Dec. 6, 1991) (codified at 29 C.F.R. § 1910.1030); *Chao v. Saw Pipes USA, Inc.*, No.

05-61089, 2007 WL 519865, 21 BNA OSHC 1905, 1907 (5th Cir. Feb. 21, 2007) (noting legislative history's support for reading of statutory language), *cert. denied*, 76 U.S.L.W. 3057 (U.S. Dec. 3, 2007) (No. 07-128).

As MetWest notes, OSHA's original notice of proposed rulemaking worded the needle-removal provision differently, stating, that "[u]sed needles . . . shall not be sheared, bent, broken, recapped, or resheathed *by hand* . . . [or] removed from disposable syringes." Occupational Exposure to Bloodborne Pathogens, 54 Fed. Reg. 23,042, 23,135 (proposed May 30, 1989) (to be codified at 29 C.F.R. § 1910.1030) (emphasis added). OSHA, however, eliminated the phrase "by hand" in its final rule implementing the BBP Standard, explaining in the preamble to that final rule that a number of commenters had misinterpreted the phrase as a complete prohibition on needle recapping or removal, rather than the prohibition on "'two-handed' or 'hand-toward-hand' actions" that OSHA intended. BBP Final Rule, 56 Fed. Reg. at 64,118. Indeed, OSHA provided an exception to the general prohibition in paragraphs (d)(2)(vii)(A) and (B) of 29 C.F.R. § 1910.1030, which allows recapping or removal of a needle with a mechanical device or one-handed technique where the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.[5] *Id.* Therefore, we find that OSHA's specific explanation of the proposed rule and the changes made in its preamble to the final rule support the plain meaning ascribed to it by the Secretary and adopted here by the judge. *See Exelon Generating Corp.*, 21 BNA OSHC 1087, 1090, 2005 CCH OSHD ¶ 32,841, p. 52,807 (No. 00-1198, 2005) (upholding "unambiguous" reading of cited standard that is consistent with structure of whole standard and its preamble).

MetWest further claims that the Secretary's reading of this provision is not entitled to deference because she has provided inconsistent interpretations of the cited provision since the promulgation of the BBP Standard. To support its contention, MetWest relies on *Union Tank Car Co.*, 18 BNA OSHC 1067, 1068-69, 1995-97 CCH OSHD ¶ 31,445, p. 44,472 (No. 96-

[5] MetWest's contention that a literal reading of the standard would illogically prohibit removal of phlebotomy needles from patients' arms and blood-filled tubes is without merit. Each of these practices satisfy the exception criteria in § 1910.1030(d)(2)(vii)(A). Indeed, removal of a needle from a patient's arm is indisputably medically necessary, as is removal of a filled blood tube from the needle-containing blood tube holder. *Cf. Manganas Painting Co.*, 21 BNA OSHC 1964, 1977, 2007 CCH OSHD ¶ 32,908, p. 53,394 (No. 94-0588, 2007) (finding standard applicable in "unusual situations where 'plain meaning' must give way in order to avert an absurd result") (citation omitted).

0563, 1997), a case in which the Commission declined to accord deference to the Secretary where the wording of the cited provision was ambiguous, and the Secretary's interpretation of the provision was inconsistent with twenty years of case law and five OSHA letters of interpretation. *Id.* In contrast, the meaning of the provision cited here is susceptible to only one literal interpretation. Accordingly, a deference analysis is not warranted, and the rationale relied upon in *Union Tank* does not apply. *E.g.*, *Consumer Prod. Safety Comm'n v. GTE*, 447 U.S. 102, 108 (1980) ("[S]tarting point for interpreting a statute is the language of the statute itself . . . [which,] absent a clearly expressed legislative intention to the contrary, . . . must ordinarily be regarded as conclusive."); *Arcadian Corp.*, 17 BNA OSHC at 1347, 1995-97 CCH OSHD at p. 42,916 ("'In a statutory construction case, the beginning point must be the language of the statute, and when a statute speaks with clarity to an issue[,] judicial inquiry into the statute's meaning, in all but the most extraordinary circumstances, is finished.'" (citations omitted)).

Moreover, the Secretary's alleged "inconsistent interpretations" relied upon by MetWest permitted the removal of contaminated needles simply because single-use (i.e., disposable) tube holders were unavailable throughout the early 1990's.[6] Thus the Secretary implicitly accepted the defense of infeasibility contained in § 1910.1030(d)(2)(vii)(A). Once those devices became generally available, OSHA notified the regulated public that it was changing its enforcement policy to require that single-use tube holders be used, unless the employer was able to make out the exceptions in § 1910.1030(d)(2)(vii)(A) and (B).[7] *See Long Island Care at Home, Ltd. v. Coke*, 127 S.Ct. 2339, 2349 (2007) (rejecting contention that regulatory interpretation contained

[6] *See* OSHA Instruction CPL 2-2.44 C (Mar. 6, 1992); Standard Interpretations 02/01/1993—*Most Frequently Asked Questions Concerning the Bloodborne Pathogen Standard*, U.S. Dep't of Labor (Feb. 1, 1993) (amended Aug. 13, 2003); Standard Interpretations 03/09/1993—*Re-useable Phlebotomy Collection Device*, U.S. Dep't of Labor (Mar. 9, 1993) (archived in 2003); OSHA Instruction CPL 2-2.44 D (Nov. 5, 1999) (replacing OSHA Instruction CPL 2-2.44 C, emphasizing prohibition on needle removal as general practice, and eliminating needle removal from blood tube holders as example of exception under § 1910.1030(d)(2)(vii)(A)).

[7] *See* OSHA Instruction CPL 2-2.69 (Nov. 21, 2001); Standard Interpretations 06/12/2002—*Re-use of Blood Tube Holders*, U.S. Dep't of Labor (June 12, 2002) ("[I]ncreased manipulation required to remove a contaminated needle from a blood tube holder is unnecessary and may result in a needlestick from either the front or back-end of the needle."); Standard Interpretations 02/01/1993—*Most Frequently Asked Questions Concerning the Bloodborne Pathogen Standard*, U.S. Dep't of Labor (Feb. 1, 1993) (amended Aug. 13, 2003); OSHA Safety and Health Information Bulletin, *Disposal of Contaminated Needles and Blood Tube Holders Used for Phlebotomy* (SHIB 10-15-03).

in internal agency memorandum constitutes "'*post hoc* rationalizatio[n]' of past agency action") (citation omitted); *Manganas Painting Co.*, 21 BNA OSHC 1964, 1975, 2007 CCH OSHD ¶ 32,908, p. 53,392 (No. 94-0588, 2007) (acknowledging relevance of emerging scientific developments to assess compliance with cited standard). *Cf. Caterpillar, Inc.*, 15 BNA OSHC 2153, 2170-73, 1991-93 CCH OSHD ¶ 29,962, pp. 41,003-04 (No. 87-0922, 1993) (acknowledging Secretary's prosecutorial discretion to alter long-standing single citation policy and issue separate citations for multiple recordkeeping violations). Under these circumstances, we agree with the judge that, since 1991, the Secretary has enforced the cited provision in a manner consistent with its plain meaning and the developing technology in this industry.[8]

II. EVIDENTIARY AND PROCEDURAL ISSUES

MetWest claims the judge improperly permitted Jane Perry to testify under Federal Rule of Evidence 702 as an expert for the Secretary, and thus should not have relied on her testimony.[9] However, whether Perry was an "expert" witness is irrelevant, in view of the fact that the judge made only two references to her testimony, neither of which involved any opinion she may have held or statement she made that was based on scientific or technical expertise. The first reference appears in the judge's discussion of OSHA's needlestick hazard determination, and relates to Perry's testimony merely summarizing 2000-2001 Exposure Prevention Information

[8] We reject MetWest's argument that OSHA's enforcement action here is prohibited by the Needlestick Safety and Prevention Act ("NSPA"), which required amendments of the BBP Standard but not with regard to the needle-removal provision. NSPA, Pub. L. No. 106-430, 114 Stat. 1901 (Nov. 6, 2000). Because OSHA's enforcement policy permitted the removal of contaminated needles from blood tube holders at the time the NSPA was promulgated, MetWest contends Congress silently amended the standard to allow one-handed needle removal. We discern no basis for such a claim. OSHA only permitted one-handed needle removal under the exceptions clause of the cited provision and did so only until single-use blood tube holders became commercially available.

Nor is MetWest's case helped by the fact that the Secretary inspected MetWest's Denver facility in 2003 and did not cite MetWest then for using the Pronto. It is well-established that "OSHA is not precluded from issuing a . . . citation for previously observed or uncited violations." *Kaspar Wire Works, Inc.*, 18 BNA OSHC 2178, 2183 n.13, 2000 CCH OSHD ¶ 32,134, p. 48,408 n.13 (No. 90-2775, 2000), *aff'd*, 268 F.3d 1123 (D.C. Cir. 2001).

[9] Federal Rule of Evidence 702 provides for the admission of expert testimony where "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue."

Network ("EPINet") needlestick tracking data.[10] Exposure to a needlestick hazard is also established independent of any testimony from Perry, as we have already concluded that Metwest's employees were exposed to such a hazard based on the undisputed fact that they removed contaminated needles from reusable blood tube holders. *See also* OSHA Safety and Health Information Bulletin, *Disposal of Contaminated Needles and Blood Tube Holders Used for Phlebotomy* (SHIB 10-15-03) (citing EPINet data in discussion of needlestick hazard associated with blood tube holders).

In addition to Perry's EPINet testimony, the judge also referenced her explanation that "throughout the 1990's new models of single use blood tube holders have been developed[,]" in part, to conclude that it was feasible for MetWest to switch to single-use blood tube holders at its Denver facility. The judge's feasibility finding is further supported by Quest's California subsidiaries' routine use of single-use blood tube holders, as well as the testimony of Quest's national director of branch operations about the availability of single-use blood tube holders. Under these circumstances, we see no error in the judge's reliance on Perry's testimony in either instance.

Finally, MetWest contends the judge erred in granting the Secretary's motion to amend the citation because the amendment "permitt[ed] the Secretary to completely change her theory of the case [. . .] in the middle of the hearing."[11] However, both the original and amended citation are premised on the same hazardous condition—exposure to needlesticks from the back-end of a contaminated needle during removal. *See Brown & Root, Inc.*, 8 BNA OSHC 1055, 1059, 1980 CCH OSHD ¶ 24,275, p. 29,569 (No. 76-3942, 1980) ("The general test for determining whether there is a change in the cause of action is whether the original and amended charges arise out of the same conduct, transaction, or occurrence." (citation omitted)). Under the

[10] Perry served for eleven years as the Director of Communication of the International Healthcare Workers Safety Center, which specializes in preventing occupational exposure to BBPs by tracking and analyzing needlestick injury data through a system called the Exposure Prevention Information Network, or EPINet system.

[11] During a six-month hearing recess, the judge granted the Secretary's motion to amend the citation and complaint over MetWest's objection. As amended, the citation describes the cited condition as MetWest's failure "to ensure that contaminated needles or other contaminated sharps were not bent, recapped or removed, in that employees removed contaminated needles from blood tube holders by activating a push-button-needle-release mechanism on each blood tube holder," rather than, as first alleged, removed contaminated needles "by hand."

amendment, all that changed was the description of the manner in which the needle is removed, which conforms to the evidence presented at the hearing.

Moreover, MetWest has made no claim that it suffered prejudice. On the contrary, when MetWest raised its opposition to the amendment during the hearing, it stated that prejudice could be avoided if the judge reopened discovery and permitted the company to amend its witness and exhibit lists, which the judge did by granting MetWest's requests to do so. *Bland Constr. Co.*, 15 BNA OSHC 1031, 1041-43, 1991-93 CCH OSHD ¶ 29,325, p. 39,401-03 (No. 87-992, 1991) (noting that any prejudice resulting from amendment is cured by providing employer a reasonable amount of time to prepare its defense). Under these circumstances, we see nothing indicating that the judge abused his discretion in granting the Secretary's amendment to the citation.

CONCLUSIONS OF LAW

Based on the foregoing analysis, we conclude that the Secretary established a violation of § 1910.1030(d)(2)(vii)(A) based on MetWest's failure to prohibit its employees from removing contaminated needles, and affirm the citation.[12] We also conclude that the judge properly relied on Perry's testimony and properly allowed the Secretary's amendment of the citation.

ORDER

We affirm the citation alleging a violation of 29 C.F.R. § 1910.1030(d)(2)(vii)(A) and assess a penalty of $1,875.

SO ORDERED.

/s/
Horace A. Thompson III
Chairman

/s/
Thomasina V. Rogers
Commissioner

Dated: December 17, 2007

[12] The parties do not dispute either the characterization of the violation or the penalty amount assessed by the judge.

SECRETARY OF LABOR, Complainant, v. METWEST, INC., a subsidiary of Quest Diagnostics, Incorporated, d/b/a Quest Diagnostics, Respondent.	OSHRC DOCKET NO. 04-0594

APPEARANCES:

For the Complainant:
Lydia Tzagoloff, Esq., Ed Falkowski, Esq., U.S. Department of Labor, Office of the Solicitor, Denver, Colorado

For the Respondent:
Brent I. Clark, Esq., Seyfarth Shaw, LLP, Chicago, Illinois

Before: Administrative Law Judge: Sidney J. Goldstein

DECISION AND ORDER

This proceeding arises under the Occupational Safety and Health Act of 1970 (29 U.S.C. Section 651-678; hereafter called the "Act").

MetWest is a wholly owned subsidiary of Quest Diagnostics, Inc., which operates more than 2,000 patient service centers nationwide (2/23/2005; Tr. 22, 59). At all times relevant to this action, Respondent, MetWest, Inc. (MetWest) maintained a place of business at 1930 South Federal, Denver, Colorado, where it was engaged in blood collection. MetWest admits it is an employer engaged in a business affecting commerce. MetWest is, therefore, subject to the requirements of the Act.

On February 6, 2004, the Occupational Safety and Health Administration (OSHA) conducted an inspection at MetWest's South Federal blood collection center. As a result of that inspection, OSHA issued a citation alleging violation of the Bloodborne Pathogens Standard at 29 C.F.R. §1910.1030(d)(2)(vii)(A). By filing a timely notice of contest MetWest brought this proceeding before the Occupational Safety and Health Review Commission (Commission). A hearing was held in Denver, Colorado over five days between February 23, 2005 and October 26, 2006. The Secretary's motion to amend the citation was granted on May 16, 2005. Briefs have been submitted on the issues, as amended, and this matter is ready for disposition.

Facts

During his inspection of MetWest's South Federal facility, OSHA Compliance Officer (CO) Cory Wilson found that MetWest's phlebotomists performed blood draws using a reusable blood tube holder

called the "Pronto." MetWest stipulates that its phlebotomists use an Eclipse needle, a Pronto blood tube holder and a number of blood tubes to draw blood. A sheathed needle is first attached to the Pronto blood tube holder. The sheath is rotated away from the "patient end" of the needle, which is inserted into the patient's vein. A stoppered blood tube is then inserted into the blood tube holder and pushed onto the hollow bore "back end" of the needle. Blood then flows into the blood tube. If more blood is required, the blood tube can be removed, and a new blood tube inserted into the Pronto holder. Phlebotomists routinely fill multiple blood tubes during a single draw. Once the blood draw is complete, the needle is withdrawn from the vein and the protective shield is rotated back into place. The needle is then discarded into a container for "contaminated sharps." The Pronto has a one handed quick release feature that separates the used needle from the blood tube holder. The phlebotomist presses a thumb against the quick release button, and allows the needle to drop into the sharps container. (02/23/2005; Tr. 36-42, 106, Exh. C-2). It is undisputed that MetWest's phlebotomists discard only the needle, retaining the Pronto blood tube holder for reuse.

OSHA has found that the reuse of blood tube holders exposes health care workers to needlesticks from the contaminated back end of phlebotomy needles (2/23/2005; Tr. 32; Exh. C-7). The International Healthcare Workers Safety Center tracks needlestick data from 90 hospitals through their EPINet system (2/24/2005; Tr. 10-16). Jane Perry, director of communications for the center, testified that between 2000 and 2001, 148 needlestick injuries caused by phlebotomy needles were reported via the EPINet system (2/24/2005; Tr. 40, 43). Twelve of the reports described injuries from the back end of the needle (2/24/2005; Tr. 40). Five reporters stated they were removing the needle from a blood tube holder (2/24/2005; Tr. 40). Employees may also be exposed to needlesticks from contacting the sharps container itself (2/24/2005; Tr. 52). Elizabeth Strock, MetWest's Environmental Health and Safety Manager, identified needlestick data collected by MetWest's parent company, Quest Diagnostics, in the regular course of its business. Quest's accident reports document back-end needlesticks sustained by phlebotomists who, 1) failed to properly dispose of needles detached from a blood tube holder (2/25/2005; Tr. 166-67; Exh. C-28 at 0300-0302), and 2) contacted the back end of needles protruding from a sharps container (2/25/2005; Tr. 173-74; Exh. C-28 at 0937-0938).

Employees sustaining a needlestick from the hollow bore back end of a phlebotomy needle may be exposed to bloodborne pathogens including HIV/Aids and hepatitis B (2/23/2005; Tr. 51, 58, 67: 2/24/2005; Tr. 153-54).

Alleged Violation of §1910.1030(d)(2)(vii)(A)

Serious citation 1, item 1, as amended, alleges:

29 CFR 1910.1030(d)(2)(vii)(A): Contaminated needles or other contaminated sharps were bent, recapped, or removed:

> **(a) METWEST, INC, a subsidiary of Quest Diagnostics, Inc., d/b/a Quest Diagnostics, 1930 South Federal Boulevard, Building B, #1A, Denver, 80219:** On or before 2/6/04, the employer did not ensure that contaminated needles or other contaminated sharps were not bent, recapped or removed, in that employees removed contaminated needles from blood tube holders by activating a push-button needle release mechanism on each blood tube holder.
>
> The cited standard provides:
>
> (vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. . ..
>
> (A) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.
>
> (B) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

Discussion

In order to prove a violation of section 5(a)(2) of the Act, the Secretary must show by a preponderance of the evidence: (a) the applicability of the cited standard, (b) the employers noncompliance with the standard's terms, (c) employee access to the violative condition, and (d) the employer's actual or constructive knowledge of the violation (*i.e.,* the employer either knew, or with the exercise of reasonable diligence could have known, of the violative condition). *Atlantic Battery Co.,*16 BNA OSHC 2131, 1994 CCH OSHD ¶30,636 (No. 90-1747, 1994).

MetWest maintains that it did not violate the cited standard because it did not "remove" contaminated needles. MetWest also maintains that the use of a single use blood tube holder would pose a "greater hazard" than the Pronto reusable holder, and that the Secretary's literal enforcement of the provisions of §1910.1030(d)(2)(vii) is precluded by the Needlestick Safety and Prevention Act. Finally, Respondent believes that the Secretary is estopped from issuing citations based on the possibility of employees sustaining needlesticks while picking up dropped phlebotomy needles.

Removal. MetWest argues that it does not "remove" contaminated needles as contemplated by §1910.1030(d)(2)(vii) and its subparagraphs (A) and (B). Though MetWest agrees that the plain meaning of the cited standard appears clear on its face, it nonetheless maintains that when the standard was finalized, the Secretary intended to limit the meaning of the word "removed" to "removed by hand using

a traditional two handed technique." According to MetWest, the Secretary always intended to permit the one-handed technique used at MetWest. MetWest argues that the Secretary has since improperly amended the cited standard by re-interpreting the meaning of "removed". MetWest argues that the Secretary, in reading "removed" in its everyday sense, amends the original standard without the publication, notice and comment required under the Administrative Procedure Act, 5 U.S.C. §553. After reviewing the record in its entirety, it can only be concluded that the Secretary's literal interpretation of the standard reasonably conforms to the purpose and wording of the standard as written, and is enforceable.

MetWest relies mainly on the preamble to the Bloodborne Pathogens (BBP) Standards at 56 Fed. Reg. 64004 (1991). The final rule states in part:

> This provision does not totally prohibit recapping or removal as the proposed standard was mistakenly interpreted to require by a number of respondents. . . . The phrase "by hand" is intended to mean 'two-handed' or 'hand-toward-hand' actions and is not intended to imply that 'one-handed' techniques or use of special devices/mechanical means to accomplish recapping or removal are prohibited.

Id. at 64118, The cited language however, is taken out of context. The text referred to is part of a summary of respondent comments addressing a recommendation by the CDC. The CDC took the position that "needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand." After taking note of the comments, the preamble found that the respondents' concerns were already adequately addressed, stating:

> After considering these comments, the Agency concluded that it is correct in the belief that recapping or removal should not be acceptable as a general practice, however certain situations exist where these actions are necessary. Therefore, paragraph (d)(2)(vii)(A) of the final standard requires that contaminated needles and other contaminated sharps shall not be removed or recapped unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.

(Exh. R-2, p. 64118). The term "by hand" was not incorporated into the standard. Paragraph (d)(2)(vii)(B) addresses the means of removal (mechanically or one-handed) that may be employed after an employer has made the required showing under (d)(2)(vii)(A).

In a March 6, 1992 Compliance Directive (CPL 2-2.44C, ¶M.4.b.[3]), OSHA reiterated the position set forth in the preamble. However, the directive specifically notes:

> Bending, recapping, or removing contaminated needles by hand is prohibited as a general practice. However, certain circumstances may exist in which these actions are necessary; e.g., . . . removing the needle from a phlebotomy collection apparatus (e.g., vacutainer).

(Exh. R-3, p. 19). It is clear from the CPL that OSHA intended to apply §1910.1030(d)(2)(vii) to the recapping and removal of needles from a phlebotomy collection apparatus, but believed that the procedure

fell under subparagraph (A), which exempts procedures for which there are no feasible alternatives. As noted by Quest Diagnostics Inc.'s national director of environmental health and safety, Clettes Lewis, no single-use blood tube holders were available on the market at the time the BBP Standard was promulgated. Lewis testified that, at that time, it would not have been feasible to comply with a flat prohibition on the removal of needles from the tube holder (10/26/2005; Tr. 13-14). Terry Jo Gile, a safety consultant testifying for MetWest, testified that had OSHA prohibited the use of reusable blood tube holders in 1991, it would have halted all blood collection. According to Gile, at that time there was no alternative to the reusable holders as "we would have run out of product to use" (10/25/2005; Tr. 195, 209-10).

In a February 1, 1993 interpretation, "Most Frequently Asked Questions Concerning the Bloodborne Pathogens Standard", OSHA again suggested that the Secretary did not believe there was a feasible alternative to recapping[1] and removing the needle from a phlebotomy collection apparatus, such as a vacutainer (Exh. R-4, p. 7).

In a November 5, 1999 enforcement directive, CPL 2-2.44D, the Secretary dropped the term "by hand" when referring to recapping and removing in reference to subparagraph (d)(3)(vii). The 1999 directive states:

> . . . Bending, recapping, or removing contaminated needles is prohibited as a general practice. Needles are expected to be used and immediately discarded, un-recapped, into accessible sharps containers. Certain circumstances may exist, however, in which recapping, bending, or removing needles is necessary.

(Exh. R-6, p. 21-22). Compliance Directive 2-2.44D also omits, without comment, any reference to phlebotomy collection apparatus.

Compliance directive 2-2.69, issued on November 27, 2001, expressly cancels CPL 2-2.44D, and sets forth the Secretary's new enforcement position with regard to phlebotomy collection apparatuses:

> . . . The practice of removing the needle from a used blood-drawing/phlebotomy device is rarely, if ever, required by a medical procedure. Because such devices involve the use of a double-ended needle, such removal clearly exposes employees to additional risk. Devices with needles must be used and immediately discarded after use, un-recapped, into accessible sharps containers.

(Exh. C-8). The effect of OSHA's 2001 enforcement policy was to require a showing by employers that no feasible alternative to removing a needle from a blood drawing device was available, as was already

---

[1] On March 9, 1993 the Secretary issued a standard interpretation in response to an inquiry about the ACCI-GUARD reusable blood tube holder. The letter states that "the user has no alternative but to recap a used needle" (Exh. R-5, p. 557). As the interpretation deals with recapping, and refers to removal only peripherally, and is of little value to this inquiry.

required under §1910.1030(d)(2)(vii)(A). OSHA followed up its 2001 Compliance Directive with a letter of interpretation dated June 12, 2002. The interpretation specifically answers the question "What is OSHA's position regarding the use of blood tube holders, specifically removing a needle in order to re-use a tube holder. Must each blood tube collection device be disposed of with the needle attached each time they are used?" Citing CPL 2-2.69, the letter states, *inter alia*:

> Removing contaminated needles and subsequently reusing blood tube holders poses multiple potential hazards. The increased manipulation required to remove a contaminated needle from a blood tube holder *is unnecessary* and may result in a needlestick from either the front or back end of the needle. According to information available from the International Health Care Worker Safety Center at the University of Virginia, injuries occurring in phlebotomy are among the highest-risk for transmitting bloodborne pathogens such as HIV, HCV and HBV, because they involve hollow-bore, blood-filled needles.
>
> Further, improper disposal of used, unprotected needle devices potentially affects more than just the user. . . close to half of all injuries from contaminated sharps occur to those who are not in immediate control of the device, but to those who come in contact with the unprotected needle downstream (e.g., nursing assistants, housekeepers, maintenance personnel). Therefore, disposing of single-use safety-activated blood collection devices decreases potential injuries downstream.

(emphasis added)(Exh. C-15). Ms. Perry explained that throughout the 1990's new models of single use blood tube holders have been developed (2/24/2005; Tr. 85). In addition the manufacture of single use devices has been stepped up. There is no longer an inadequate supply of the devices (2/24/2005; Tr. 67). Quest Diagnostics Inc. subsidiaries in California routinely use single utilize a single use blood tube holder manufactured by Sims Portex (2/25/2005; Tr. 24-25). It would be feasible to switch to single use blood holders at MetWest's South Federal facility (2/25/2005; Tr. 47, 62-63). In 2003 OSHA issued an additional safety and health information bulletin, which states:

> While most conventional blood tube holders can be reused multiple times, in order to best control worker exposure to blood, *most healthcare facilities discard the entire device*, with needle attached after each use. . . . Because the reuse of tube holders requires the removal of used needles, exposing healthcare workers to contaminated, unsafe, back-end needles, professional phlebotomists have been urged not to reuse holders.
>
> OSHA has concluded that the best practice for prevention of needlestick injuries following phlebotomy procedures is the use of a sharp with engineered sharps injury protection (SESIP) (e.g., safety needle) attached to the blood tube holder and the immediate disposal of the entire unit after each patient's blood is drawn.

(Emphasis added)(Exh. C-7). The Secretary's 1993 interpretation of the BBP standards was amended in 2003 to reflect OSHA's revised enforcement policy (Exh. R-4). Both Quest Diagnostics and MetWest were aware of OSHA's revised enforcement policy; Clettes Lewis was familiar with OSHA's publications

as well as the trade news releases concerning the BBP (10/26/2005; Tr. 47, 85-86). He knew that in September, 2002, MetWest received citations for alleged violations of §1910.1030(d)(2)(vii)(A) after OSHA conducted inspections at various laboratory sites in Colorado (10/26/2005; Tr. 58-59, 82; Exh. R-24; see also testimony of Andrea Hernandz, MetWest's regional safety manager; 10/25/2005; Tr. 82). Though the citations were withdrawn while OSHA reviewed its policy, MetWest was given no reason to believe that OSHA revised its most recent position on the removal of phlebotomy needles from blood tube holders (10/26/2005; Tr. 92-95).

The records in evidence clearly document the Secretary's consistent interpretation of the cited standard. The plain language of §1910.1030(d)(2)(vii) prohibits, and has always prohibited the removal of contaminated needles unless no feasible alternative is available. The Secretary has never suggested, in any of its many BBP publications, that it intended to limit the term "removal" to "two-handed or hand-toward-hand removal". As noted by Complainant, such a reading would render subparagraphs (A) and (B) meaningless. The Supreme Court has held that "the Commission is authorized to review the Secretary's interpretations only for consistency with the regulatory language and for reasonableness." *Martin v. OSHRC*, 499 U.S. 144, 154, 111 S.Ct 1171, 1179 (1991). Where, as here, the Secretary's interpretation literally tracks the standard's language, there appears to be no need for further inquiry.

MetWest, however, argues that the Commission's decision in *Union Tank Car Co.*, 18 BNA OSHC 1067, 1997 CCH OSHD ¶31,445 (No. 96-0563, 1997) dictates a different result. In *Union Tank Car Co.* the Commission found that §1910.132(a)'s requirement that employers "provide" personal protective equipment (PPE), could not be interpreted to mean "pay for." *Id.* In that case, the Secretary's interpretation flew in the face of 20 years of precedent, including: 1) a Commission case, *The Budd Co.,* 1 BNA OSHC 1548, 1973-74 CCH OSHD ¶17,389 (No. 199, 1974) (consolidated), *affd*, 513 F.2d 201 (3d Cir. 1975) specifically holding that "provide" did not mean "pay for"; 2) five letters of interpretation stating that the standard did not specify who pays the cost of protective equipment; and 3) an intervening notice of proposed rulemaking and revised final rule in which the Secretary failed to squarely place the cost of compliance on the employer. The Secretary first communicated her new position, *i.e.,* that employer's were responsible for paying for PPE, in a directive issued less than 18 months prior to the inspection that lead to the subject citation. The Secretary failed to elaborate the policy considerations that led to the change in her interpretation of the standard in any of her subsequent publications. Under those circumstances, the Commission refused to find that the Secretary's new interpretation of the cited standard was reasonable.

Union Tank Car Co. is clearly distinguishable from this case. The Secretary, as discussed above, has consistently interpreted §1910.1030(d)(2)(vii)(A) since the promulgation of the BBP Standard in 1991. There is no support for MetWest's contention that OSHA intended, at the time of §1910.1030(d)(2)(vii)'s promulgation, or at any time since, to limit the plain meaning of "remove" to "two-handed removal techniques". What has changed is not the agency's position regarding the standard's meaning, but the availability of single use blood tube holders for use with phlebotomy collection apparatuses. OSHA specifically stated in 1992 that removal of the needle from a phlebotomy collection apparatus may be necessary. In 2001, as it became clear that the removal of needles from blood drawing apparatus was no longer required by a medical procedure, the agency revised its enforcement policy. In 2003, OSHA clarified its policy, noting that blood tube holders were now routinely discarded with the needle after a single use.

Unlike the Secretary's about-face in *Union Tank Car,* the Secretary's decision to cite employers removing phlebotomy needles from reusable blood tube holders is not a change in an interpretive rule. Because the Secretary's current enforcement policy does not add content to the governing regulation, and merely sets forth the agency's position with respect to how it will treat, *i.e.,* enforce, the governing standard, no notice and comment is required. *Hudson v. FAA,* 192 F.3d 1031 (D.C. Cir 1999); *see also*, *Air Transport Ass'n of America, Inc. v. F.A.A.*, 291 F.3d 49 (D.C. Cir 2002)[Agency policy statement is exempt from notice and comment requirements where the statement merely spells out a duty fairly contained within the regulation the policy purports to construe].

MetWest removed phlebotomy needles from reusable tube holders at its South Federal facility. It has not shown that no alternative is feasible, or that such action is medically required. A violation of the standard has been established.

Needlestick Safety and Prevention Act. On November 6, 2000 Congress passed the Needlestick Safety and Prevention Act, which revised portions of the Bloodborne Pathogen Standard, enhancing the provisions of 29 CFR §1910.1030(c), which requires employees to maintain an Exposure Control Plan designed to minimize employee exposure. The mandated changes appear at paragraph (c)(1)(iv) and state that annual review of the required plans shall:

> (A) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and
> (B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(2/23/2006; Tr. 24; Exh. R-7). Paragraph (d)(2)(vii) was not modified in any way.

Respondent, in effect, maintains that the Congressionally amended requirements of §1910.1030 (c)(1)(iv)(A) and (B) conflict with the Secretary's strict enforcement of (d)(2)(vii) and its subparagraphs (A) and (B). MetWest states that after the consideration of the available blood collection technology, it determined that the use of Pronto reusable blood tube holders reduces employee exposure to bloodborne pathogens, and must be implemented pursuant to paragraph (c)(1)(iv)(B).

Paragraphs (c)(1)(iv) and (d)(2)(vii) of the BBP standard are not facially incompatible, and MetWest has provided no authority to the contrary. Paragraph (c)(1)(iv), as amended by the Needlestick Act requires only that employers annually consider the implementation of safer medical devices as they become technologically feasible and commercially available. Both the employer's deliberations and any changes in its operations must be documented in its Exposure Control Plan. The amended standard does not compel employers to substitute their judgment for that of the Secretary, or authorize them to disregard the express requirements of the BBP standard.

The Secretary's enforcement of the specific requirements of §1910.1030(d)(2)(vii) is not precluded by the Needlestick Safety and Prevention Act.

Greater Hazard. MetWest contends that utilization of a single use blood tube holder would expose its phlebotomists to an increased risk of needlesticks. Elaine Phillips, the national director of branch operations for Quest Diagnostics, testified that single use devices are difficult to dispose of and produce an increased volume of biohazard waste. The additional waste increases the needlestick danger for personnel handling disposal (2/24/2005; Tr. 206-214, 225). In addition, switching over to any new system creates an increased risk of needlesticks until personnel become accustomed to the new equipment (2/25/2005; Tr. 56-57, 66-68). Phillips maintained that after evaluating the SIMS Portex Needle Pro, a single use device, and the BD Eclipse with a Pronto holder, Quest determined that the Eclipse/Pronto was the safest device (2/24/2005; Tr. 203-04).

In order to establish the affirmative defense of a greater hazard, the employer must show that 1) the hazards of compliance are greater than the hazards of non-compliance; 2) alternative means of protection are unavailable; and 3) an application for a variance would be inappropriate. *See Walker Towing Corp.*, 14 BNA OSHC 2072, 2078, 1991-93 CCH OSHD ¶29,239, p. 39,161 (No. 87-1359, 1991). MetWest has not shown the single use device poses a greater hazard than the BD Eclipse/Pronto device. MetWest's needlestick records were shown to be incomplete; moreover MetWest failed to provide evidence of the statistical significance of its analysis of those records (10/25/2005; Tr. 124-27, 132-36; Exh. R-31). In addition, Quest's data shows that their phlebotomists ranked the SIMS Portex and the BD Single Use holder as high or higher than the Eclipse/Pronto device (Exh. C-4, p. 59). As noted above,

some Quest subsidiaries already use single use blood tube holders (2/25/2005; Tr. 24-25). The BD Eclipse/Pronto was chosen not because it was safer, but because of BD's "product innovation in the pipeline, willingness to partner, pricing and our long-term relationship with BD." (2/25/2005; Tr. 48; Exh. C-4, p. 59).

In any event, MetWest's failure to apply for a variance for regularly performed operations obviates need to address the first two elements of the defense. *Spancrete Northeast, Inc.*, 15 BNA OSHC 1020, 1991 CCH OSHD ¶29,313 (No. 86-521, 1991). MetWest does not maintain that requesting a variance would have been futile. MetWest has not established the affirmative defense of greater hazard.

Estoppel. MetWest maintains that OSHA should be estopped from arguing here that forceps are an inadequate means of dealing the biohazard resulting from dropped needles. After inspecting another MetWest location in April, 2003, OSHA issued a citation for a violation of §1910.1030(g)(2)(vii)(F). The citation alleged a training violation arising out of a MetWest employee's representation that he would use his fingers to pick up a needle that missed the sharps container. The citation was settled after Respondent revised its Exposure Control Plan, and retrained its employees in the proper means of disposing of hazardous waste (2/25/2005; Tr. 117-25; Exh. R-26). Ms. Strock testified that the investigating CO did not object to the use of the Pronto reusable blood tube holder; moreover, he believed the only way an employee could get a back end needlestick was by picking up a disposable needle that missed the sharps container (2/25/2005; Tr. 125; Exh. R-27). Following her conversations with the CO, Strock believed it was OSHA's position that the removal of needles from a Pronto reusable blood tube holder was permissible (2/25/2005; Tr. 130).

The purpose of collateral estoppel is to foreclose the re-litigation of issues decided in prior litigation. *ConAgra Flour Milling Co.,* 16 BNA OSHC 1137, 1153 (No. 88-1250, 1993). Collateral estoppel is not an appropriate remedy here, where the Respondent has never before litigated the contested issue. The Secretary is not, therefore, estopped from enforcing the cited standard.

Penalty

A penalty of $1,875.00 was proposed for this item. CO Cory Wilson testified that the severity of the violation was high in that the potential exposure to HIV or Hepatitis B could result in death (2/23/2005; Tr. 67). Two phlebotomists at the facility were exposed to the cited hazard. One told Wilson that she used each blood tube holder approximately 30 times before disposing of it, the other reused a blood tube holder only a couple of times (2/23/2005; Tr. 37-38). Wilson did not believe the probability of an accident occurring was high, as they utilized work practices designed to minimize the chance of a needlestick. Because MetWest has a good safety program CO Wilson included a 15% reduction for good faith in his calculation of the proposed penalty.

The proposed penalty is appropriate and will be assessed.

ORDER

1. Serious citation 1, item 1, alleging violation of 29 CFR §1910.1030(d)(2)(vii)(A) is AFFIRMED, and a penalty of $1,875.00 is ASSESSED.

/s/
Sidney J. Goldstein
Judge, OSHRC

Dated: May 5, 2006