COMMISSIONER OF LABOR OF

THE STATE OF NORTH CAROLINA,

COMPLAINANT,

v.

BEFORE THE NORTH CAROLINA OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

DOCKET NO. OSHANC 2005-4523 OSHA INSPECTION NO. 308758523 CSHO ID NO. K2192

ORDER

BRITTHAVEN, INC., DBA BRITTHAVEN OF PIEDMONT,

RESPONDENT.

DECISION OF THE REVIEW COMMISSION

This appeal was heard at or about 10:00 A.M. on the 13th day of February, 2007 in Room 124, First Floor, Old YWCA Building, 217 West Jones Street, Raleigh, North Carolina by Oscar A. Keller, Jr., Chairman, Dr. Richard G. Pearson and Janice Smith Gerald, Members of the North Carolina Occupational Safety and Health Review Commission.

APPEARANCES

Larissa Ellerbee, Assistant Attorney General, North Carolina Department of Justice, Raleigh, North Carolina for the Complainant.

Eric P. Lindberg, Associate General Counsel for Britthaven, Garner, North Carolina for the Respondent.

ISSUES PRESENTED

1. Did Complainant prove by the greater weight of the evidence that the Respondent violated 29 CFR 1910.1030(f)(1)(ii)(D) by failing to perform follow up Hepatitis B vaccine titer testing in accordance with the recommendations of the U. S. Public Health Service, Center for Disease Control?

STATUTES AND REGULATIONS AT ISSUE

1. 29 CFR 1910.1030(f)(1)(ii)(D), reads as follows:

(f) Hepatitis B vaccination and post-exposure evaluation and follow-up.

(1) General

(i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis are:

- A. Made available at no cost to the employee;
- B. Made available to the employee at a reasonable time and place;
- C. Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and
- D. Provided according to the recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

2. Recommendations of the U.S. Public Health Service in pertinent part:

HCP who have contact with patients or blood and are at ongoing risk for percutaneous injuries should be tested 1-2 months after completion of the 3-dose vaccination series for anti-HBs (21). Persons who do not respond to the primary vaccine series (i.e., anti-HBs <10 mIU/mL) should complete a second 3-dose vaccine series or be evaluated to determine if they are HbsAg-positive. Revaccinated persons should be retested at the completion of the second vaccine series. Persons who do not respond to an initial 3-dose vaccine series have a 30%-50% chance of responding to a second 3-dose series (165). Persons who prove to be HbsAg-positive should be counseled regarding how to prevent HBV transmission to others and regarding the need for medical evaluation (12,163,166). Nonresponders to vaccination who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or probable parenteral exposure to HBsAg-positive blood.

CENTERS FOR DISEASE CONTROL AND PREVENTION. UPDATED U.S. PUBLIC HEALTH SERVICE GUIDELINES FOR THE MANAGEMENT OF OCCUPATIONAL EXPOSURES TO HBV, HCV, AND HIV AND RECOMMENDATIONS FOR POSTEXPOSURE PROPHYLAXIS. MMWR 2001;50(No. RR-11):16.

3. 29 CFR 1910.6(a)(1) states:

The standards of agencies of the U.S. Government, and organizations which are not agencies of the U.S. Government which are incorporated by reference in this part, have the same force and effect as other standards in this part. Only the mandatory provisions (i.e. provisions containing the word "shall" or other mandatory language) of standards incorporated by reference are adopted as standards under the Occupational Safety and Health Act.

4. 29 CFR 1910.6(a)(2) states:

Any changes in the standards incorporated by reference in this part and an official historic file of such changes are available for inspection at the national office of the Occupational Safety and Health Administration, U.S. Department of Labor, Washington, DC 20210.

5. 1910.6(a)(3) states:

The materials listed in paragraphs (b) through (w) of this section are incorporated by reference in the corresponding sections noted as they exist on the date of the approval, and a notice of any change in these materials will be published in the Federal Register. These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

6.5 U.S.C. 552(a) states in pertinent part:

Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public--

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

7.1 CFR part 51states:

Sec. 51.1 Policy.

(a) Section 552(a) of title 5, United States Code, provides, in part, that ``matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register."

(b) The Director will interpret and apply the language of section 552(a) together with other requirements which govern publication in the Federal Register and the Code of Federal Regulations. Those requirements which govern publication include--

(1) The Federal Register Act (44 U.S.C. 1501 et seq.)

(2) The Administrative Procedure Act (5 U.S.C. 551 et seq.);

(3) The regulations of the Administrative Committee of the Federal Register under the Federal Register Act (1 CFR Ch. I); and

(4) The acts which require publication in the Federal Register (See CFR volume entitled ``CFR Index and Finding Aids.")

(c) The Director will assume in carrying out the responsibilities for incorporation by reference that incorporation by reference---

(1) Is intended to benefit both the Federal Government and the members of the class affected; and

(2) Is not intended to detract from the legal or practical attributes of the system established by the Federal Register Act, the Administrative Procedure Act, the regulations of the Administrative Committee of the Federal Register, and the acts which require publication in the Federal Register.

(d) The Director will carry out the responsibilities by applying the standards of part 51 fairly and uniformly.

(e) Publication in the Federal Register of a document containing an incorporation by reference does not of itself constitute an approval of the incorporation by reference by the Director.

(f) Incorporation by reference of a publication is limited to the edition of the publication that is approved. Future amendments or revisions of the publication are not included.

Sec. 51.3 When will the Director approve a publication?

(a) The Director will approve the incorporation by reference of a publication when the following requirements are met:

(1) The publication is eligible for incorporation by reference (See Sec. 51.7).

(2) The language of incorporation meets the requirements of this part (See Sec. 51.9).

(3) The publication is on file with the Office of the Federal Register.

(4) The Director has received a written request from the agency to approve the incorporation by reference of the publication.

(b) The Director will notify the agency of the approval or disapproval of an incorporation by reference within 20 working days after the agency has met all the requirements for requesting approvals (See Sec. 51.5).

Sec. 51.5 How does an agency request approval?

(a) Formal approval of a publication for incorporation by reference applies to a final rule document. For timely approval by the Director of the Federal Register, the agency must--

(1) Make a written request for approval at least 20 working days before the agency intends to submit the final rule document for publication;

(2) Send with the written request a copy of the final rule document that uses the proper language of incorporation; and

(3) Ensure that a copy of the publication is on file at the Office of the Federal Register.

(b) Agencies may consult with the Office of the Federal Register at any time with respect to the requirements of this part.

Sec. 51.7 What publications are eligible?

(a) A publication is eligible for incorporation by reference under 5 U.S.C. 552(a) if it--

(1) Conforms to the policy stated in Sec. 51.1;

(2) Is published data, criteria, standards, specifications, techniques, illustrations, or similar material;

(3) Substantially reduces the volume of material published in the Federal Register; and

(4) Is reasonably available to and usable by the class of persons affected by the publication. In determining whether a publication is usable, the Director will consider--

(i) The completeness and ease of handling of the publication; and

(ii) Whether it is bound, numbered, and organized.

(b) The Director will assume that a publication produced by the same agency that is seeking its approval is inappropriate for incorporation by reference. A publication produced by the agency may be approved, if, in the judgment of the Director, it meets the requirements of paragraph (a) and possesses other unique or highly unusual qualities. A publication may be approved if it cannot be printed using the Federal Register/Code of Federal Regulations printing system.

(c) The following materials are not appropriate for incorporation by reference:

(1) Material published previously in the Federal Register.

(2) Material published in the United States Code.

Sec. 51.9 What is the proper language of incorporation?

(a) The language incorporating a publication by reference shall be as precise and complete as possible and shall make it clear that the incorporation by reference is intended and completed by the final rule document in which it appears.

(b) The language incorporating a publication by reference is precise and complete if it-

(1) Uses the words ``incorporated by reference;"

(2) States the title, date, edition, author, publisher, and identification number of the publication;

(3) Informs the user that the incorporated publication is a requirement;

(4) Makes an official showing that the publication is in fact available by stating where and how copies may be examined and readily obtained with maximum convenience to the user; and

(5) Refers to 5 U.S.C. 552(a).

(c) If the Director approves a publication for incorporation by reference, the agency must--

(1) Include the following under the DATES caption of the preamble to the final rule document (See 1 CFR 18.12 Preamble requirements):

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of -----.

(2) Includes the term ``incorporation by reference" in the list of index terms (See 1 CFR 18.20 Identification of subjects in agency regulations).

Sec. 51.11 How does an agency change or remove an approved incorporation?

(a) An agency that seeks approval for a change to a publication that is approved for incorporation by reference must--

(1) Publish notice of the change in the Federal Register and amend the Code of Federal Regulations;

(2) Ensure that a copy of the amendment or revision is on file at the Office of the Federal Register; and

(3) Notify the Director of the Federal Register in writing that the change is being made.

(b) If a regulation containing an incorporation by reference fails to become effective or is removed from the Code of Federal Regulations, the agency must notify the Director of the Federal Register in writing of that fact within 5 working days of the occurrence.

In this Article, unless the context otherwise requires:

8. N.C.G.S. 95-127 title "Definitions" states in pertinent part:

(15) The term "occupational safety and health standards" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, safety devices, operations or processes reasonably necessary and appropriate to provide safe and healthful employment and places of employment, and shall include all occupational safety and health standards adopted and promulgated by the Secretary which also may be and are adopted by the State of North Carolina under the provisions of this Article. This term includes but is not limited to interim federal standards, consensus standards, any proprietary standards or permanent standards, as well as temporary emergency standards which may be adopted by the Secretary, promulgated as provided by the Occupational Safety and Health Act of 1970, and which standards or regulations are published in the Code of Federal Regulations or otherwise properly promulgated under the federal agencies.

Emphasis added.

9. N.C.G.S. 95-131 title "Development and promulgation of standards; adoption of federal standards and regulations" states in pertinent part:

(a) <u>All occupational safety and health standards promulgated under the federal act by the Secretary</u>, and any modifications, revision, amendments or revocations in accordance with the authority conferred by the federal act or any other federal act or agency relating to safety and health and adopted by the Secretary, <u>shall be adopted as the rules of the Commissioner of this State unless the Commissioner decides to adopt an alternative State rule as effective as the federal requirement</u> and providing safe and healthful employment in places of employment as required by the federal act and standards and regulations heretofore referred to and as provided by the Occupational Safety and Health Act of 1970. <u>Chapter 150B of the General Statutes governs the adoption of rules by the Commissioner</u>.

Emphasis added.

10. N.C.G.S. 150B-21.5 titles "Circumstances when notice and rule-making hearing not required" states in pertinent part:

(c) OSHA Standard. - The Occupational Safety and Health Division of the Department of Labor is not required to publish a notice of text in the North Carolina Register or hold a public hearing when it proposes to adopt a rule that concerns an occupational safety and health standard and is identical to a federal regulation promulgated by the Secretary of the United States Department of Labor. The Occupational Safety and Health Division is not required to submit to the Commission for review a rule for which notice and hearing is not required under this subsection.

Having reviewed and considered the record and the briefs of the parties and the arguments of the parties, the North Carolina Occupational Safety and Health Review Commission hereby REVERSES the decision of the Hearing Examiner and makes the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. This case was initiated by a notice of contest which followed citations issued to the Respondent to enforce the Occupational Safety and Health Act of North Carolina (OSHANC or Act), N.C. Gen. Stat. §§ 95-126 et seq.

2. The Commissioner of Labor (Complainant) is responsible for enforcing OSHANC (N.C. Gen. Stat § 95-133).

3. The Respondent is an employer within the meaning of N.C. Gen. Stat § 95-127(10).

4. The Respondent, Britthaven, Inc dba Britthaven of Piedmont is subject to the provisions of OSHANC (N.C. Gen. Stat § 95-128).

5. The Respondent, Britthaven Inc., operating under the trade name of Britthaven of Piedmont, is the owner and operator of a long term nursing facility located in Albemarle, North Carolina,

6. On March 16, 2005 Safety Compliance Officer Peggy Reme began a complaint inspection at Respondent's worksite located at 33426 Old Salisbury Road in Albemarle, North Carolina.

7. On April 18, 2005, as a result of the inspection, Complainant issued two citations to Respondent, the one which is the subject of this appeal is Citation 1, Item 1 for an alleged serious violation of 29 CFR 1910.1030(f)(1)(ii)(D) for the failure to perform follow up Hepatitis B vaccine titer testing in accordance with the recommendations of the U. S. Public Health Service, Center for Disease Control.

8. Respondent administered the first 3-dose Hepatitis B vaccination series to qualified Health Care Personnel as is required by 29 CFR 1910.1030(f)(1)(i) and as recommended by the U. S. Public Health Service pursuant to 29 CFR 1910.1030(f)(1)(ii)(D).

9. Respondent did not do follow-up testing to determine which of the employees who received the first series of three vaccinations failed to produce sufficient protective antibodies as a result of the first series of Hepatitis B vaccinations as is required by 29 CFR 1910.1030(f)(1)(i) and as recommended by the U. S. Public Health Service pursuant to 29 CFR 1910.1030(f)(1)(ii)(D). (Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11):15-16).

10. The follow-up testing to identify those employees who failed to produce sufficient protective antibodies is necessary so that they may be offered a second series of three vaccinations to help them produce sufficient protective antibodies or be evaluated to see if they are infected with Hepatitis B (HbsAg-positive) as is required by 29 CFR 1910.1030(f)(1)(i) and as recommended by the U. S. Public Health Service pursuant to 29 CFR 1910.1030(f)(1)(i)(D). (Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11):16).

11. After the second series of three vaccinations, the revaccinated employees should be retested to determine if they have produced sufficient protective antibodies to the Hepatitis B virus. (Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11):16).

12. Employees who do not produce sufficient protective antibodies to the Hepatitis B virus after the first 3-dose vaccine series have a 30 to 50 percent chance of producing sufficient protective antibodies to the Hepatitis B virus after the second 3-dose vaccine series. (Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11):16).

13. Employees who are infected with the Hepatitis B virus (HbsAg-positive) should be counseled on the need for medical evaluation and on how to prevent the transmission of the Hepatitis B virus to others. (Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11):16).

14. Employees who do not produce sufficient protective antibodies to the Hepatitis B virus as a result of the second vaccination series should be considered susceptible to Hepatitis B virus infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain Hepatitis B Immune globulin (HBIG) prophylaxis for any known or probable exposure to parenteral exposure to blood infected with Hepatitis B virus (HbsAg-positive blood). (Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11):16).

15. A notice of contest dated May 27, 2005 and contesting Citation 1, Item 1 was received from Respondent and filed with the Review Commission on June 2, 2005.

16. This matter was scheduled for hearing on November 16, 2005 in Charlotte, North Carolina before Hearing Examiner Richard M. Koch.

17. Prior to the hearing, the Attorney for the Complainant and the Attorney for the Respondent conferred and decided that an evidentiary hearing was not required and they would submit their legal arguments in pre-hearing briefs.

18. On or about November 9, 2005, a pre-hearing telephone conference was conducted in which this proposal was submitted to Hearing Examiner Koch. Judge Koch instructed the parties to jointly prepare and submit a set of stipulations and to individually prepare pre-hearing briefs.

19. The parties submitted Stipulations of Fact on or about December 6, 2005.

20. The Complainant and Respondent both submitted their pre-hearing briefs on or about December 30, 2005.

21. On April 28, 2006, Hearing Examiner Koch issued his order dismissing Citation 1, Item 1, the alleged serious violation of 29 CFR 1910.1030(f)(1)(ii)(D) for failing to perform follow up Hepatitis B vaccine titer testing in accordance with the recommendations of the U.S. Public Health Service, Center for Disease Control.

22. Citation 2, Item 2, a nonserious violation of 29 CFR 1910.132(d)(2) which was not contested was affirmed in Judge Koch's order.

23. Judge Koch's order was filed with the Review Commission on May 8, 2006.

24. Complainant filed its Petition for Review and Motion for Stay with the Review Commission on June 7, 2006.

25. On June 22, 2006, Chairman Keller granted Complainant's Petition for Review and Motion for Stay.

26. The parties filed their briefs and the appeal was heard at the February 13, 2007 Quarterly meeting of the Review Commission.

27. The Commission adopts the Hearing Examiner's findings of fact numbered 1 through 6 and 8 through 10.

28. The Commission adopts the Hearing Examiner's findings of fact numbered 12 and 13.

29. The Commission adopts the Hearing Examiner's finding of fact numbered 15 and 17.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, the Commission concludes as a matter of law as follows:

1. The foregoing findings of fact are incorporated as conclusions of law to the extent necessary to give effect to the provisions of this Order.

2. The Commission has jurisdiction of this cause and the parties are properly before this Commission.

3. The standard, 29 CFR 1910.1030(f)(1)(ii)(D) requirement that the "hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis" be provided "according to the recommendations of the U.S. Public Health Service" was not an incorporation by reference of a standard of the U.S. Public Health Service within the meaning of 29 CFR 1910.6(a)(1) et seq.

4. 29 CFR 1910.6(a)(1) does not apply to 29 CFR 1910.1030(f)(1)(ii)(D).

5. The Complainant has proven by the greater weight of the evidence and by substantial evidence that the Respondent violated 29 CFR 1910.1030(f)(1)(ii)(D) by failing to perform follow up Hepatitis B vaccine titer testing in accordance with the recommendations of the U.S. Public Health Service, Center for Disease Control.

DISCUSSION

The scope of review for errors of fact is the whole record test. Brooks v. Snow Hill Metalcraft Corporation, 2 NCOSHD 377 (RB 1983). N.C. Gen. Stat § 95-135(i) states that upon appeal to the Review Commission "the Commission shall schedule the matter for hearing, on the record, (emphasis added) except that the Commission may allow the introduction of newly discovered evidence, or in its discretion the taking of further evidence upon any question or issue." "De novo review is applied for errors of law. Commissioner v. Tuttle Enterprises dba James Fleming Tank Company, 5 NCOSHD 115, at 117 (RB 1993), citing, Brooks v. Maxton Hardwood Corporation, 2 NCOSHD 277 (RB 1981).

The determination of this case involves the interpretation of an OSH regulation and is therefore entirely a question of law and <u>de novo</u> review is applicable. As the Hearing Examiner indicated in his decision, this appears to be a case of first impression, at least for the North Carolina courts. The Hearing Examiner below found that the Complainant had failed to prove that the Respondent was required by 29 CFR 1910.1030(f)(1)(ii)(D) to require its health care personnel who have contact with patients or blood and are at ongoing risk for percutaneous injuries to be tested 1-2 months after completion of the 3-dose Hepatitis B vaccination series. The Hearing Examiner bases his conclusion on whether the recommendations of the Public Health Service can be incorporated by reference and enforced through an OSH regulation. He states:

At issue is the plain language of the cited standard, which would seem to make the recommendation of the United States Public Health Service a mandatory standard. This language collides with the language of 29 CFR 1910.6, which seems to require that only mandatory language

(the word "shall") in standards or guidelines incorporated into OSH standards become enforceable.

This was the argument of the Respondent and the Hearing Examiner agreed with the Respondent's position.

Both the Hearing Examiner and the Respondent incorrectly applied 29 CFR 1910.6(a)(1) to 29 CFR 1910.1030(f)(1)(ii)(D). The provisions of 29 CFR 1910.6(a)(1) just do not apply. There is an extensive set of requirements for incorporating a standard by reference that is set out in 1 CFR part 5. These requirements among many others involve the use of the correct language, "incorporation by reference", written request by the involved agency and approval by the Director of the Federal Register. It is clear that the federal Department of Labor did not attempt or intend for 29 CFR 1910.1030(f)(1)(ii)(D) to incorporate by reference the provisions of the Public Health Service uses the terms "shall" or "should" is just irrelevant. The Respondent is right in his assertion that 29 CFR 1910.6(a)(1) provisions with respect to "incorporate by reference" apply to the entire Part 1910, the general industry standards, however, Respondent is wrong in his assertion that 29 CFR 1910.1030(f)(1)(ii)(D) was an attempt to incorporate by reference the provisions of the Public Health Service with respect to the administration of the Hepatitis B vaccine.

29 CFR 1910.1030(f)(1)(i) requires that "T[t]he employees who have had an exposure incident." The term "vaccination series" is not defined but the fact that it uses the term "series" denotes that more than one shot is required but the length of time between shots and the number of shots is not given. The employer would have to look to an outside source to determine what "vaccination series" means and the most logical if not the only source would be the current practice of the medical community. The latest recommendations of the U.S. Public Health Service's recommendation to give a second series of shots is based on the results of research published in the New England Journal of Medicine. As a basis for recommending that a second series of shots be given, the U.S. Public Health Service states "Persons who do not respond to an initial 3-dose vaccine series have a 30%-50% chance of responding to a second 3-dose series" and as authority for that an article published in the New England Journal of medicine is cited in Footnote 165. CENTERS FOR DISEASE CONTROL AND PREVENTION. UPDATED U.S. PUBLIC HEALTH SERVICE GUIDELINES FOR THE MANAGEMENT OF OCCUPATIONAL EXPOSURES TO HBV, HCV, AND HIV AND RECOMMENDATIONS FOR POSTEXPOSURE PROPHYLAXIS. MMWR 2001;50(No. RR-11):16.

29 CFR 1910.1030(f)(1)(ii)(D)'s requirement that the vaccination series be "[P]provided according to the recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place" just gives a uniform source that the employer can consult to determine what constitutes a "vaccination series" according to the current practice of the medical community and ensures that if the employer follows the current recommendations of the USPHS, he will be in compliance with the Bloodborne Pathogen Standard with respect to Hepatitis B vaccinations. The Preamble to the Bloodborne Pathogen Standard is in agreement with this reasoning with the statement:

Paragraph (f)(1)(ii)(D) requires that evaluations and procedures be provided according to recommendations of the U. S. Public Health Service (USPHS), current at the time these evaluations and procedures take place, except as specified by this paragraph (f). The CDC, an agency of the USPHS, follows the epidemiology of bloodborne pathogens, and periodically revises and updates its guidelines and recommendations. At the time of publication of this rule, CDC is the USPHS agency responsible for issuing guidelines and making recommendations regarding infectious agents referred to in this standard as bloodborne pathogens. The proposed rule had specified that evaluations and procedures be done according to standard recommendations for medical practice. The Visiting Nurse Corporation stated that the "provision of effective post-exposure prophylaxis according to standard recommendations of the U. S. Public Health Service" (Ex. 20-1268). The American Medical Association (AMA) noted that OSHA should "defer to the federal scientific agency with the most expertise" and "believes that the best strategy for reducing the risk of occupational transmission of bloodborne disease is implementations of the CDC for prevention of HIV transmission in healthcare settings" (Tr. 12/19/89, p. 982; Ex. 160). The American Association of Critical-Care Nurses commendations would provide consistency" (Ex. 20-1162).

Preamble to Bloodborne Pathogens, 56 FR 64013 (Dec. 6, 1991). As noted above in the quote from the Preamble to Bloodborne Pathogens, the proposed rule had provided that "standard recommendations for medical practice" be followed but three medical advisory groups, including the American Medical Association, agreed that the recommendations of the U.S. Public Health Service be followed for clarity, expertise and consistency. Subsection "D" is not a provision that is incorporated by reference and does not become a new regulation requiring rule making if the U.S. Public Health Service changes its policy on vaccination. It just gives a clear, consistent and definitive source for the current medical practice for giving the Hepatitis B vaccination series, the current practice that the employer is already mandated to do by 29 CFR 1910.1030(f)(1)(i)'s requirement that the employer "make available the hepatitis B vaccination series to all employees who have occupational exposure".

Respondent cites the case law which held that the use of the mandatory language "shall" in an OSH regulation incorporating by reference an ANSI standard that is phrased in non-mandatory language "should" does not change the ANSI standard into a mandatory regulation. See, e.g. Marshall v. <u>Pittsburgh-Des Moines Steel Co.</u>, 584 F.2d 638 (3rd Cir. 1978); <u>Secretary of Labor v. Brown & Root</u>, 1980 WL 10697 (OSHRC), 9 O.S.H. Cas. (BNA) 1027. Respondent argues that although these cases arise in a different context, they stand for "the broader proposition that non-mandatory advisory recommendations issued by outside organizations cannot be converted into binding and enforceable occupational and safety standards". Respondent's brief, p. 14. This is not what has happened in this case. An advisory Public Health Service recommendation has not been converted into a binding OSH standard, the recommendations of the Public Health Service are just the source for the employer to find a clear, definitive and consistent statement of the current practice of the medical community with respect to the giving of the Hepatitis B vaccination series, The employer shall make available the hepatitis B vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident." See the discussion in the previous paragraph.

The Complainant argues that deference should be given to the Commissioner's interpretation of the regulation and the Respondent argues that the meaning of 29 CFR 1910.6(a)(1) is clear and that no deference should be given the agency's interpretation. Respondent also argues that the Commissioner's interpretation is not reasonable and therefore should not be given any deference. There are several rules of statutory or regulatory construction that are applicable here. In <u>Walker v. Fleetwood Homes</u>, 176 N.C. App. 668, Judge Jackson in her concurring in part and dissenting in part decision, set out the general rules of statutory construction used by the North Carolina Courts:

Our Supreme Court has held that "a statute dealing with a specific situation controls, with respect to that situation, [over] sections which are general in their application." In re Charnock, 358 N.C. 523, 529, 597 S.E.2d 706, 710 (2004) (quoting State ex rel. Util. Comm'n v. Lumbee River Elec. Membership Corp., 275 N.C. 250, 260, 166 S.E.2d 663, 670 (1969)). "In such situation the specially treated situation is regarded as an exception to the general provision." State ex rel. Util. Comm., 275 N.C. at 260, 166 S.E.2d at 670 (citation omitted). "This rule of construction is especially applicable where the specific provision is the later enactment." Id.

When two statutes "deal with the same subject matter, they must be construed in <u>pari materia</u> and harmonized to give effect to each." <u>State ex rel. Util. Comm.</u>, 275 N.C. at 260, 166 S.E.2d at 670 (quoting <u>Gravel Co. v. Taylor</u>, 269 N.C. 617, 620, 153 S.E.2d 19, 21 (1967)). However, when the statute "dealing with a specific matter is clear and understandable on its face, it requires no construction." Id. (citing <u>Highway Commission v. Hemphill</u>, 269 N.C. 535, 153 S.E.2d 22 (1967); <u>Davis v. Granite Corporation</u>, 259 N.C. 672, 131 S.E.2d 335 (1963); <u>Long v. Smitherman</u>, 251 N.C. 682, 111 S.E.2d 834 (1960)).

Walker v. Fleetwood Homes, 176 N.C. App. 668, at ____(2006) (Judge Jackson, dissenting and concurring).

Those principles that are applicable to statutes are equally applicable to regulations. Applying those principals above to the two regulations so as to give effect to both. Applying the Respondent's interpretation would result in part of 29 CFR 1910.1030(f)(1)(ii)(D) being declared invalid and would go against the rules of statutory construction and the admonition that the agency that created the regulation or regulations that have no meaning. When one interpretation would mean that one of the regulations would be held invalid and another interpretation would give meaning to both of the regulations, then the interpretation that allows both to be valid is the one to be applied. The Commissioner's interpretation that 29 CFR 1910.6(a)(1) does not apply to 29 CFR 1910.1030(f)(1)(ii)(D) although the Commission has agreed with the Commissioner of Labor that 29 CFR 1910.6(a)(1) does not apply to 29

Also, 29 CFR 1910.1030(f)(1)(ii)(D) deals with a specific situation, the use of the recommendations of the Public Health Service for the source of the current practice of the medical community for the administering of the Hepatitis B vaccinations while the provisions of 29 CFR 1910.6(a)(1) deal with a general situation, the incorporation by reference of standards of agencies of the U.S. Government, and organizations which are not agencies of the U.S. Government into the General Industry Standards. Interpreting 29 CFR 1910.1030(f)(1)(ii)(D) so that it is does not incorporate by reference a standard of the Public Health Service allows the specific situation with respect to the Hepatitis B vaccinations to control over the general provision that deals with incorporation by reference of standards of agencies and organizations and allows both regulations to be given effect. The Commissioner's interpretation merits deference and the application of the standard rules of statutory construction show that it is a reasonable interpretation.

Respondent also argues that "irregardless [sic-regardless] of the outcome of this decision, Hepatitis B vaccinations will still be provided to healthcare personnel under the supervision of licensed personnel, thereby obviating much of the concern expressed by Complainant". (Respondent's brief, p. 16). Respondent, however, fails to point out that there will be no uniformity in practice among the different physicians and licensed personnel with different degrees of protection given to the employees according to the particular practice of the individual healthcare personnel. Respondent also fails to take into account that class of people who do not respond to the first series of vaccinations. By failing to give the follow up titer testing, the employees who failed to produce sufficient antibodies are not identified and neither are the employees who did not respond to the first series of security in that they assume that since they took the vaccinations they are protected. More importantly, those that did not respond to the second series of three vaccinations have a 30% to 50% chance of producing protective antibodies after the second series. Those that do not respond to the second series need to take to avoid Hepatitis B infection and the need to take prophylaxis action in the event of a probable Hepatitis B infection to employees.

Respondent also suggests several regulatory changes that the Complainant could undertake to amend the standard to require the follow up testing and second series of vaccinations. The answer to that is that the standard is not broken and is in no need of fixing. The standard was clear as to what was required and that is to give the vaccination series and to look to the current recommendations of the Public Health Service for the current practice of the medical community. If Respondent did not think that the standard applied to it, it could have requested a variance from the regulation or it could have requested a standards interpretation letter. Respondent itself ignored a regulatory procedure when they failed to request a variance from the procedure and decided for themselves not to follow the standard. Knowing what a standard requires and consciously refusing to follow it has been held to be grounds for a willful violation. See, Associated Mechanical Contractors, Inc., 342 N.C. 825, 467 S.E.2d 398 (1996).

The parties have stipulated that the penalty of \$1,375.00 was correctly calculated and is reasonable as alleged. The Commission has reviewed the 4 statutory criteria of N.C.G.S. 95-138(b), the size of the business, the gravity of the violation, the good faith of the employer and the record of previous violations and has found the assessed penalty of \$1,375.00 to be appropriate.

ORDER

For the reason stated herein, the Review Commission hereby **ORDERS** that the Hearing Examiner's April 28, 2006 Order in this cause is, **REVERSED** and the Respondent is found to have committed a serious violation of 29 CFR 1910.1030(f)(1)(ii)(D) with a penalty of \$1,375.00 as alleged in Citation 1, Item 1 for the failure to perform follow up Hepatitis B vaccine titer testing in accordance with the recommendations of the U. S. Public Health Service, Center for Disease Control and is **ORDERED** to pay the penalty of \$1,375.00 within 30 days of the date of this order.

This the 24th day of July, 2007.

OSCAR A. KELLER, JR., CHAIRMAN

RICHARD G. PEARSON, MEMBER