

OHIO DEPARTMENT OF HEALTH

246 North High Street
Post Office Box 118
Columbus, Ohio 43216-0118
Telephone: (614) 466-3543
www.odh.state.oh.us



BOB TAFT
Governor

J NICK BAIRD, M.D.
Director of Health

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March 19, 2001

Stephen Solomon
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
2 White Flint
Rockville, Maryland 20852

Dear Mr. Solomon:

I am writing in regard to the NRC review and comment that is currently occurring for Ohio's draft Chapter 3701:1-50 Transportation. This chapter of rules is designed to be consistent with the transportation standards found in 10 C.F.R. 71. The issue raised is that Ohio's draft transportation standard does not address deliberate misconduct. I understand that you have indicated that this results in a lack of compatibility between Ohio and NRC. I also understand that Jim Lynch has indicated that this issue is a matter of compatibility that will be raised during Ohio's upcoming IMPEP review scheduled for the week of May 14, 2001. I have reviewed this issue with the department's Office of General Counsel and they concur with the information in this letter.

Ohio licenses facilities that handle radioactive material. As such, information that is submitted to the Ohio Department of Health is done in the name of the facility—not an individual. The licensee is responsible for the accuracy of the information regardless of any deliberate misconduct on the part of one of their employees, contractors, or suppliers. Rule 3701:1-40-05 provides that "All information provided to the director by an applicant for a license or a licensee and all information required to be maintained by the applicant or the licensee in accordance with license conditions or by Chapter 3748. of the Revised Code or rules adopted thereunder, shall be complete and accurate in all material respects."

If the director were to determine that information submitted by an individual was deliberately falsified, inaccurate, or incomplete, the director could take action to suspend or revoke the license, refuse to issue the license, seek criminal or civil penalties against the licensee, and/or seek injunctive relief. In any order the director issued to the licensee, the director could require that the licensee take action to ensure that information submitted by their employees, contractors, or suppliers was accurate and complete. The typical action against the employee, contractor, or licensee is the responsibility of the licensee and not the Ohio Department of Health directly to the individual unless the Ohio Department of Health also licenses that individual such as in a nuclear medicine technologist or radiation therapy technologist application. The actions taken against a licensee could also be taken against an applicant or an entity that is licensable pursuant to Chapter 3748 of the Revised Code. It is exceedingly difficult for me to believe that any licensee or applicant would not take action to ensure that his or her employee, contractor, or supplier was no longer in a position to submit falsified, inaccurate, or incomplete information—particularly if the facility's license to operate hung in the balance.

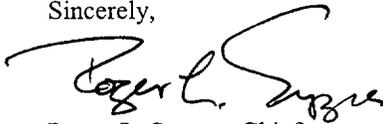
Ohio has previously provided some information to you regarding how the Ohio Department of Health handles violations that are deliberate. This is found at paragraph (I)(2) and (I)(3) of Rule 3701:1-38-05 of the Ohio Administrative Code. NRC reviewed this rule during Ohio's agreement state application process. Ohio also submitted a copy of the Enforcement Program for the agreement state program as a part of Ohio's application. In that document one of the actions listed as potentially being taken by the Director of Health is suspension of a radioactive material license or request suspension of employee of licensee from work involving radioactive material. These documents are enclosed. In addition to these specific matters,

Ohio has the ability to issue orders to individuals and entities to compel compliance with Chapter 3748 of the Ohio Revised Code. The language of division (B)(2) of section 3748.05 of the Ohio Revised Code provides broad powers to the Director of Health in that the Director of Health may... "exercise all incidental powers necessary to carry out the purposes of this chapter and the rules adopted under it including, without limitation, the issuance of orders" (emphasis added). Chapter 3748 of the Ohio Revised Code is the chapter of law in Ohio that deals with matters of radiation protection. If necessary, an order could be issued to an individual who is not a licensee of the department.

NRC has chosen to adopt specific rules regarding deliberate misconduct. The Ohio Department of Health has chosen to adopt certain aspects of deliberate misconduct into rule through the administrative penalty rule specified previously. For certain other aspects the Ohio Department of Health has chosen to remain flexible, and maintain a position that all information submitted to the Ohio Department of Health is done in the name of the licensee and the licensee or applicant is responsible for the information even if an employee or contractor deliberately submitted false, inaccurate, or incomplete information. The NRC deliberate misconduct rule is specified as level "C" compatibility. As such, Ohio has discretion to meet the objectives of the deliberate misconduct rule in a different manner than NRC. Ohio believes that through the use of standards and the application of orders issued by the director to individuals, licensees, applicants, or licensable facilities that the essential objectives of the NRC deliberate misconduct rule are met and there is no issue of compatibility between Ohio and NRC in regard to deliberate misconduct.

Please advise if any additional information is necessary to resolve this matter. If I may provide further information to bring this matter to conclusion, please contact me at 614-644-2727.

Sincerely,



Roger L. Suppes, Chief
Bureau of Radiation Protection

Cf: Jim Lynch, Region III, U.S. NRC
Socrates Tuch, Office of General Counsel

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orders, the licensee has the right to request a hearing to determine the appeal of the Administrative penalties as specified in sections 119.01 to 119.19 of the Revised Code. The licensee must request this hearing within 30 days of the time of the mailing of the administrative penalty assessment. The hearing for administrative penalties will be conducted as outlined above for orders.

SPECIFIC ACTIONS OF THE DEPARTMENT OF HEALTH IN THE ENFORCEMENT POLICY

Chapter 3748. of the Revised Code and rules 3701-38-06 and 3701-38-05 of the Administrative Code provide certain specific actions that may be taken by the Department of Health as Enforcement Actions. Appendix 2, *Specific Actions, Enforcement Diagram, Chart #2* of this program provides a graphic flow diagram of the decision tree for actions to be taken by the Department of Health in the event a violation of State statute or rule is determined. All actions taken, however, are as a result of a written Notice of Violation. A Notice of Violation is a written notice setting forth one or more violations of a legally binding requirement. The Notice of Violation normally requires the recipient to provide a written statement describing:

1. the reasons for the violation or, if contested, the basis for disputing the violation;
2. corrective steps that have been taken and the results achieved;
3. corrective steps that will be taken to prevent recurrence; and
4. the date when full compliance will be achieved.

The director may waive all or portions of a written response to the extent relevant information has already been provided to the director in writing or documented in an inspection report. The director may require responses to Notices of Violation to be made under oath. Normally, responses under oath will be required only in connection with Severity Level I, II, or III violations or adjudication or emergency adjudication orders.

The director uses the Notice of Violation as the usual method for formalizing the existence of a violation. Issuance of a Notice of Violation is normally the only enforcement action taken, except in cases where the criteria for issuance of Administrative Penalties and orders, as set forth in this section and *Administrative Penalties* are met. However, special circumstances regarding the violation findings may warrant discretion being exercised such that the director refrains from issuing a Notice of Violation.

In addition, licensees are not ordinarily cited for violations resulting from matters not within their

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control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors.

The actions that may be taken by the director include, but are not limited to:

- Administrative monetary Penalties;
- Suspension of licensee (or request for suspension of employee of licensee) from work involving radioactive material;
- suspension of a license for radioactive materials;
- revocations of a license for radioactive materials;
- civil actions and penalties; and
- criminal actions and penalties.

The director may, in the event that sources of radioactive material have been found abandoned, or otherwise improperly stored, used or disposed of and the owner can not be identified or located, issue an order requiring the impoundment of the sources. If, in the opinion of the director, an emergency exists where the health and safety of the public is involved, the director may issue an emergency order for the impoundment of the sources of radioactive material. Following impoundment, the director is authorized to make any disposition of the sources of radioactive material as is delineated in chapter 3748. of the Revised Code and the rules that have been adopted under this statute.

Administrative Penalties

An Administrative Penalty is a monetary penalty that may be imposed for violation of:

1. certain specified licensing provisions of the Ohio Revised Code, the rules promulgated thereunder or adjudication or emergency adjudication orders issued by the director;
2. any requirement for which a license may be revoked; or
3. reporting requirements under Ohio Administrative Code.

Administrative Penalties are designed to deter future violations both by the involved licensee as well as by other licensees conducting similar activities and to emphasize the need for licensees to identify violations and take prompt comprehensive corrective action.

Administrative Penalties are considered for all violations. In addition, Administrative Penalties will

TWENTY-FIVE PER CENT AND CONTINUE TO INCREASE THE PENALTY BY AN ADDITIONAL TWENTY-FIVE PER CENT FOR EACH SUBSEQUENT OCCURRENCE.

- (H) WHEN A VIOLATION OCCURS AND THE FACILITY IDENTIFIES THE VIOLATION BEFORE IT RESULTS IN AN EVENT OR IS CITED BY THE DEPARTMENT, THE DIRECTOR MAY REDUCE THE PENALTY SPECIFIED IN PARAGRAPH (C) OF THIS RULE AS FOLLOWS:
- (1) IN THE CASE OF A FACILITY THAT IDENTIFIED THE VIOLATION AS A RESULT OF OBSERVATION, THE DIRECTOR MAY REDUCE THE ADMINISTRATIVE MONETARY PENALTY ASSESSED IN ACCORDANCE WITH PARAGRAPH (C) OF THIS RULE IN AN AMOUNT OF UP TO TWENTY-FIVE PER CENT.
 - (2) IN THE CASE OF A FACILITY THAT DISCOVERED THE VIOLATION AS A RESULT OF A SELF-MONITORING EFFORT, SUCH AS AN AUDIT, TEST, SURVEILLANCE, DESIGN REVIEW, OR TROUBLE SHOOTING, THE DIRECTOR MAY REDUCE THE ADMINISTRATIVE MONETARY PENALTY ASSESSED IN ACCORDANCE WITH PARAGRAPH (C) OF THIS RULE IN AN AMOUNT UP TO FIFTY PER CENT.
 - (3) IN THE CASE OF A FACILITY THAT SELF-CORRECTS A SEVERITY III OR IV VIOLATION IN A MANNER AND TIME PERIOD APPROVED BY DIRECTOR, THE DIRECTOR SHALL NOT ISSUE AN ADMINISTRATIVE MONETARY PENALTY.
- (I) NOTWITHSTANDING ANY OTHER PROVISION IN THIS RULE, AFTER DETERMINATION OF THE SEVERITY LEVEL OF A VIOLATION FOUND BY THE DEPARTMENT, THE DIRECTOR MAY INCREASE THE AMOUNT OF THE ADMINISTRATIVE MONETARY PENALTY AS FOLLOWS:
- (1) IN THE CASE OF OVERALL PAST POOR FACILITY PERFORMANCE THE ADMINISTRATIVE MONETARY PENALTY ASSESSED IN ACCORDANCE WITH PARAGRAPH (C) OF THIS RULE MAY BE INCREASED UP TO ONE HUNDRED PER CENT.
 - (2) IN THE CASE OF A VIOLATION THAT IS FLAGRANT OR RECKLESS AND THAT RESULTS IN A SUBSTANTIAL INCREASE IN RISK TO PERSONNEL, THE GENERAL PUBLIC OR THE ENVIRONMENT, INCLUDING CASES IN WHICH THE DURATION OF THE VIOLATION HAS CONTRIBUTED TO THE SUBSTANTIAL INCREASE IN RISK, THE ADMINISTRATIVE MONETARY PENALTY ASSESSED IN

ACCORDANCE WITH PARAGRAPH (C) OF THIS RULE MAY BE INCREASED UP TO ONE HUNDRED PER CENT.

- (3) IN THE CASE OF A WILLFUL VIOLATION WITHIN THE ADMINISTRATIVE CONTROL OF THE LICENSEE, THE ADMINISTRATIVE MONETARY PENALTY ASSESSED IN ACCORDANCE WITH PARAGRAPH (C) OF THIS RULE MAY BE INCREASED UP TO ONE HUNDRED PER CENT.
- (J) THE FACILITY MAY APPEAL THE ASSESSMENT OF AN ADMINISTRATIVE MONETARY PENALTY IN ACCORDANCE WITH CHAPTER 119 OF THE REVISED CODE, PROVIDED THAT THE FACILITY REQUESTS A HEARING WITHIN THIRTY DAYS OF RECEIVING NOTICE OF THE ADMINISTRATIVE PENALTY ASSESSMENT. THE DIRECTOR MAY CONSOLIDATE A HEARING ON AN ADMINISTRATIVE MONETARY PENALTY ASSESSED UNDER THIS RULE WITH ANY OTHER COMPLAINT OR FINDING OF THE DIRECTOR WHERE THE DIRECTOR DETERMINES THAT THERE ARE ONE OR MORE ISSUES OF FACT OR LAW IN COMMON. NO MORE THAN ONE HEARING WILL BE CONDUCTED WITH RESPECT TO EACH VIOLATION ALLEGED.

Effective date:

R.C. 119.032 Review Date:

Certified by:

Lou Ellen Fairless
Director of Health

Date

Promulgated under: R.C. Chapter 119

Rule authorized by: section 3748.05

Rule amplifies: sections 3748.04 to 3748.07, 3748.09 to 3748.11,
3748.13, and 3748.15 to 3748.17

Prior effective date: none