

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
DIVISION OF ENVIRONMENTAL HEALTH  
BUREAU OF COMMUNITY ENVIRONMENTAL HEALTH

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IN RE: Petition for Variance Under  
Section 120.542, Florida  
Statutes, Filed by:

David Squalli, Representing  
ECODAS  
Petitioner.

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ORDER GRANTING  
PETITION FOR VARIANCE

Pursuant to section 120.542, Florida Statutes, on September 9, 2005, David Squalli, representing ECODAS, (Petitioner), filed a Petition for Variance from Florida Administrative Code Rule 64E-16.002(2)(e), regarding biomedical waste treatment. Notice of the petition was published by the Department of Health in the Florida Administrative Weekly on February 10, 2006. The department requested additional information which was received on April 17, 2006. No comments from interested persons were received.

Upon consideration of the petition and supporting evidence, the Department of Health, Division of Environmental Health, Bureau of Community Environmental Health (Department), makes the following findings of facts and conclusions of law.

FINDINGS OF FACT

1. Florida Administrative Code Rule 64E-16.004(2)(e), requires biological indicators be placed in specified locations within a load of untreated biomedical waste for the purpose of demonstrating treatment efficacy upon completion of the treatment cycle.
2. Petitioner is a biomedical waste treatment unit manufacturer.
3. The design and operation of the Petitioner's treatment unit, which involves an internal shredding system, makes Petitioner unable to comply with the requirement in Florida

Administrative Code Rule 64E-16(2)(e), for specified placement and maintenance of biological indicators.

4. Petitioner proposes a protocol to meet the intent of Florida Administrative Code Rule 64E-16.002(2)(e), through monitoring internal temperatures and placing biological indicators into a small wire basket that hangs below the shredder and into the middle of the load of waste to be treated. The basket will be hung before a treatment cycle is begun. When the treated waste is emptied, the biological indicators will be removed from the basket and incubated for verification of treatment efficacy.
5. Petitioner alleges that application of Florida Administrative Code Rule 64E-16.002(2)(e), creates a substantial economic hardship for the Petitioner because Petitioner could not sell their treatment unit in Florida.
6. Petitioner alleges that their proposal for monitoring internal temperatures and placing biological indicators in a wire basket in the center of the untreated biomedical waste load meets the intent of the underlying statute, section 381.0098, F.S., to protect the public health by maintaining safe standards for the management of biomedical waste.

#### CONCLUSIONS OF LAW

7. Pursuant to section 120.542, Florida Statutes, state agencies are authorized to grant variances and waivers to requirements of their rules when the party subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means and that application of the rule would create a substantial hardship or violate principles of fairness.
8. Florida Administrative Code Rule 64E-16.002(2)(e), was promulgated to implement s. 381.0098, Florida Statutes, and s. 381.006(8), Florida Statutes.

9. The primary purpose of s. 381.0098, Florida Statutes, and s. 381.006(8), Florida Statutes, is to protect the public health by establishing standards for the safe management of biomedical waste.

CONCLUSIONS

10. The primary purpose of s. 381.0098, Florida Statutes, and of s. 381.006(8), Florida Statutes, will be met by Petitioner's protocol for temperature monitoring and placement of biological indicators in a wire basket suspended in the middle of the waste load to be treated.

11. The Petitioner would suffer a substantial economic hardship if Florida Administrative Code Rule 64E-16.004(2)(e), was applied because compliance with this Rule would prevent the Petitioner from selling its biomedical waste treatment unit in Florida.

WHEREFORE, based on the forgoing, the Petition for Variance filed by David Squalli, representing ECODAS, is hereby GRANTED.

DONE and ORDERED this 13 day of June, 2006, in Tallahassee, Leon County, Florida.

By:

  
Eric J. Grimm, M.P.A., Chief  
Bureau of Community Environmental Health

### NOTICE OF RIGHTS TO APPEAL

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. Chapter 28-106, Florida Administrative Code, governs such proceedings. A petition for a hearing must be in writing and must be received by the Agency Clerk for the Department within twenty-one (21) days from receipt of this order. The address for the Agency Clerk is 4052 Bald Cypress Way, BIN #A02, Tallahassee, Florida 32399-1703. The Agency Clerk's facsimile number is (850) 410-1448.

Mediation is not available as an alternative remedy.

Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a 'final order'.

Should this order become a 'final order', a party who is adversely affected by it is entitled to judicial review pursuant to section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of the rendition of the final order.

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing has been sent by U.S. Mail, interoffice mail, or hand delivery to each of the below-named persons this 15<sup>th</sup> day of June, 2006.



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