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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

May 31, 2002

Honorable Robert Zimmerman, Jr., Secretary
Department of Health
802 Health and Welfare Building
Harrisburg, PA 17108

Re: Regulation #10-166 (IRRC #2185)
Department of Health
Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts
and Perinatal Exposure of Newborns to HIV

Dear Secretary Zimmerman:

We received your letter informing us of your intent to toll the review of the subject regulation and your revisions to the regulation on May 31, 2002. The Commission has no objection.

Pursuant to Section 5.1(g)(3) of the Act (71 P.S. § 745.5a(g)(3)), the Committees will now have until June 10, 2002, to complete their review. The Commission will act on this regulation at its public meeting on June 13, 2002.

If you have any questions, please contact me at 783-5506 or bobn@irrc.state.pa.us.

Sincerely,

Robert E. Nyce
Executive Director
wbg

cc: Honorable George T. Kenney, Jr., Majority Chairman, House Health and Human Services Committee
Honorable Frank L. Oliver, Democratic Chairman, House Health and Human Services Committee
Honorable Harold F. Mowery, Jr., Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
Nia Wilson, Legal Counsel, House Health and Human Services Committee
Stanley Mitchell, Chief Counsel, House Health and Human Services Committee
David J. DeVries, Esq., Office of Attorney General
Stephen F. Tuckey, Esq., Office of General Counsel

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and Perinatal Exposure of Newborns to HIV

Dear Secretary Zimmerman:

On May 31, 2002, we discussed several issues related to this final-form regulation with the Department's Chief Counsel, Lori McLaughlin. These issues can be resolved through the tolling procedure. Therefore, we recommend that you consider tolling the review period to make the following revisions.

1. In a list of the information that must be reported, including name, address, sex, date of test etc., Section 27.32a(b)(2)(xiii) requires "any other information the Department determines to be relevant." The phrase should be deleted.
2. Section 27.32A(a)(1), as written, can be interpreted to require laboratories to report all CD4 T-Lymphocyte test results, regardless of the reporting limit specified in Section 27.22(b). A cross-reference to the requirements in Section 27.23 should be added.
3. Section 27.22(c) uses the phrase "unless otherwise provided for in this chapter." The phrase should be deleted. Alternatively, the specific citations to pertinent provisions Chapter 27 should be added.
4. Information on the process for site qualification to become a "State-designated anonymous HIV-testing site" should be added. If there are published guidelines that must be met, the Department should reference their location, and indicate where they can be obtained.

If the Department chooses to toll the review period, it must deliver written notice to both the Standing Committees and the Commission on the same day. The written notice must be delivered

Honorable Robert Zimmerman, Jr. Secretary
May 31, 2002
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prior to any Standing Committee action on the regulation, or before the end of the Standing Committee's review period on June 4, 2002, whichever occurs first.

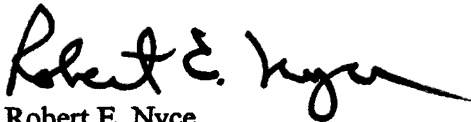
As required by Section 307.5 of our regulations, written notice must include:

1. A citation to the section(s) the Department is considering revising,
2. A description of the revisions being contemplated, and
3. An explanation of how the revisions will satisfy our concerns.

If the Commission objects to tolling the review period, we will notify you and the Standing Committees within two business days after receipt of your tolling notice. In the event the Commission objects to your tolling notice, the review period will not be tolled and your regulation will be considered by the Commission at our public meeting on June 13, 2002. If the Commission does not object, the review period is tolled for up to 30 days beginning with receipt of your letter and ending on the day you resubmit the regulation.

If you have any questions, please call me at 783-5506.

Sincerely,



Robert E. Nyce
Executive Director

wbg

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Honorable Frank L. Oliver, Democratic Chairman, House Health and Human Services Committee
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