STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

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Commissioner

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Roswell Park Cancer Institute
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DOH GC Opinion No. 04-02
Laboratory Retention of Specimens

Dear Ms. Hanley:

This is in response to your November 6, 2003 letter requesting on opinion on the application of 10 NYCRR §58-1.11 to Roswell Park Cancer Institute's ("Roswell Park") proposed arrangements with other hospitals and laboratories regarding the retention of slides and specimens.

As stated in your letter, Roswell Park often requests original pathology slides and specimens from hospitals and laboratories to insure an accurate diagnosis has been made and to determine an appropriate plan of care and treatment for the patient. Roswell Park also needs to retain portions of the materials for future patient management, conference presentations and educational purposes. You have asked whether the Department of Health regulations permit a hospital or laboratory to transfer slides and specimens to Roswell Park with the understanding Roswell Park would return the slide or specimen to the original laboratory within twenty-four (24) hours of a request from that laboratory. In the alternative, you have asked whether Department regulations permit a laboratory to make a re-cut of the original specimen for Roswell Park's permanent pathology files.

You have cited 10 NYCRR §58-1.11(c) and (d) in your letter as creating a potential conflict in this area. 10 NYCRR §58-1.11(c) provides:

> "All records and reports of tests performed including the original or duplicates of original reports received from another

> laboratory shall be kept on the premises of both laboratories and shall be exhibited to representatives of the department upon request...Records which are required to be retained for more than two years may, after two years, be stored off the immediate laboratory premises, provided they can be available to the laboratory staff or other authorized person in the laboratory within 24 hours of a request for records."

Subdivision (d) of the same section governs the retention of specimens and states:

> "Specimens shall be retained so as to be accessible to the laboratory within 24 hours for at least the period set forth below:..."

Since your question relates solely to the retention and potential transfer of specimens, the language contained in subdivision (d) is controlling. The language in subdivision ©) does not apply since the regulation establishes standards for the retention of specimens that are separate and distinct from those applicable to laboratory records. Implicit in the requirement that specimens shall be "accessible to the laboratory within 24 hours" is an expectation that specimens may be stored off the premises of the laboratory as long as the laboratory maintains sufficient control over such specimens to be able to produce them within 24 hours of a request. Nothing in the regulation limits where specimens might be located as long as they are stored in accordance with the standards set forth in the regulation and are accessible within 24 hours. There is nothing in the statute or regulation that precludes this requirement from being fulfilled through the execution of a contract with another health care provider or laboratory that can store the specimen in an appropriate manner and retrieve and transfer it to the original facility within the specified 24 hour period.

Your alternative proposal of asking the original laboratory to provide Roswell Park with a portion of the tissue specimen is also acceptable as long as the original laboratory maintains the portion of the tissue on which the report is based and retains any other tissue that is not needed by the requesting or consulting hospital or laboratory. The Department has recognized in 10 NYCRR §58-1.13 (c)(7) that pathology slides are often referred out for consultation by providing "all slides referred for consultation must have the patient's name and other identifiers written on the label." When a new re-cut is used for the purposes of a consultation, the receiving laboratory would be required to maintain the slide under 10 NYCRR 58-1.11(d) since it is issuing a report based upon that specimen. Further, the original laboratory would not be required to maintain control over the re-cut since it did not use that portion of the specimen as the basis of its report. However, appropriate records should be maintained concerning the disposition of the original tissue.

If you have any further questions regarding this matter, please feel free to contact Judy L. Doesschate, Esq. of my staff at (518) 473-1403.

Very truly yours,

Donald P. Berens, Jr.
General Counsel