



DIVISION OF PUBLIC HEALTH

Jim Doyle  
Governor

1 WEST WILSON STREET  
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Karen E. Timberlake  
Secretary

**State of Wisconsin**

Department of Health Services

608-266-1251  
FAX: 608-267-2832  
TTY: 888-701-1253  
dhs.wisconsin.gov

September 18, 2009

Oncology Systems, Inc.  
Attn: Ms. Jennifer Williams, Regulatory Affairs  
206 North Randolph Street, Suite 301  
Champaign, IL 61820

Dear Ms. Williams:

This refers to the inspection and investigation authorized by ss. 254.31- 254.45, Stats. conducted by Chris Timmerman and Leola Dekock of this office on August 13, 2009 into the activities of Oncology Systems at Wheaton-Franciscan Healthcare – All Saints, Racine, WI. This facility is an Agreement State licensee in Wisconsin Department of Health Services' jurisdiction. The findings from the inspection were reviewed with the licensee and John Kordomenos during our exit briefing conducted on August 13, 2009.

Based on the information developed during the inspection and the investigation, the DHS has determined that two violations of DHS 157 requirements occurred. These violations are cited in the enclosed Notice of Non-Compliance.

Specifically, the violations involve: (a) the installation of a Nucletron microSelectron-Classic HDR unit without a specific license to do so and (b) failing to notify the DHS at least 3 days prior to engaging in licensed activities, the installation of high dose rate after loaders on two separate occasions, in accordance with DHS 157.14(2).

During the inspection, it was brought to Mr. Kordomenos' attention that radioactive materials license number LA-11598-L01, issued by the Louisiana DEQ, had been terminated on June 29, 2009 at the request of your company. The termination of a radioactive materials license does not invalidate the former licensee's liability for actions taken under the license. It was also brought to Mr. Kordomenos' attention that Wisconsin has been an Agreement State since August 2003.

There are potential safety consequences associated with the first violation. The significance stems from the installation of a high dose rate afterloading unit without having been specifically licensed or trained to do so. The potential for danger to occupational or public health is significant. Your actions have caused Wheaton-Franciscan Healthcare – All Saints to be in violation of DHS regulations (DHS 157.67(3)(a)).

Although there were no actual safety consequences associated with the second violation, the Department considers failure to notify DHS significant because without this information, the DHS

is not aware of licensed activities being conducted in DHS jurisdiction and, therefore, can not inspect these activities. This impedes the department's ability to carry out its mission to protect the public health and safety.

Submit a written statement or explanation in reply including:

- (1) Corrective actions that have been taken by you and the results achieved.
- (2) Corrective actions which will be taken to avoid further items of noncompliance.
- (3) The date when full compliance will be achieved. This report shall be received by this office before November 18, 2009.

The DHS may assess a forfeiture (i.e. fine) of \$ 2500.00 for each Severity level 3 violation [DHS157.90 (2)]. Each day of continued violation constitutes a separate offense.

DHS has evaluated the information you and your representatives presented at the enforcement conference held September 17, 2009. The DHS has decided to assess a forfeiture of \$ 5000.00; \$2500.00 for each violation.

#### Appeal Rights

In response to the forfeiture, you have the following options:

1. If you choose to pay the forfeiture, remit payment within **10 days of receipt of this notice** to the following address:

Department of Health Services  
Radiation Protection Section  
P.O. Box 2659  
Madison, WI 53701-2659

Certified mail may be sent to:

Department of Health Services  
Radiation Protection Section  
1 West Wilson Street, Rm. 150  
Madison, WI 53702-0007

2. If you choose to contest the forfeiture, send to the division of hearings and appeals, **within 10 days after receipt of this notice**, a written request for hearing under s. 227.44, Stats. The hearing request shall contain all of the following:
  - a. Name and address of the person filing the request
  - b. The license number
  - c. Reason for the hearing request

- d. Relief sought
- e. A copy of any notice issued by the department that is the subject of the action

On the date the hearing request is sent to the division of hearings and appeals, the petitioner shall send a copy of the hearing request to the DHS. [DHS 157.91(4)]

This is to advise you that you are required to post the enclosed notice of non compliance of radiological working conditions and your response to DHS [DHS 157.88(1)(c)].

If you have any questions or concerns regarding this inspection, please contact Cheryl K. Rogers, Radioactive Materials Program, Supervisor at (608) 266-8135 or [Cheryl.Rogers@wisconsin.gov](mailto:Cheryl.Rogers@wisconsin.gov) .

Sincerely,

Paul Schmidt, Chief  
Radiation Protection Section  
Encl.

CC: NRC Region III  
NRC Region I  
Louisiana Dept. of Environmental Quality  
Illinois EMA, Radioactive Materials Section



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**NOTICE OF NON COMPLIANCE**

Oncology Systems, Inc.  
Radioactive Material License Number LA-11598-L01

Based on the results of the Wisconsin Department of Health Services, Radiation Protection Section investigation and inspection at Wheaton-Franciscan Healthcare – All Saints, Racine, WI, license number 101-1299-01, conducted on August 13, 2009, certain of your activities are not in compliance with Wisconsin Administrative Code, Chapter DHS 157 ‘Radiation Protection’ as indicated below:

1. Contrary to DHS 157.67(3)(a), a remote afterloader unit was installed by an unauthorized company not specifically licensed by the Department, NRC or an Agreement State to perform installation, maintenance or repairs on a remote afterloader unit. Specifically, on February 10, 2009, Oncology Systems installed a Nucletron microSelectron Classic remote afterloader unit at the Wheaton-Franciscan Healthcare-All Saints facility in Racine, Wisconsin.

This is a Severity Level 3 violation.

2. Contrary to DHS 157.14(2), Oncology Systems, Inc., a licensee of Louisiana, installed remote afterloader units in Racine, Wisconsin, an Agreement State, without notifying the Department of Health Services in writing or paying the prescribed fees. Specifically, on August 30, 2008, an AccuSource 1000 remote afterloader and on February 10, 2009, a Nucletron microSelectron Classic remote afterloader were installed at the Wheaton-Franciscan Healthcare-All Saints facility in Racine, Wisconsin.

This is a Severity Level 3 violation.