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ARRA INFORMATION NOTICE 2016-IN-01: TO INFORM HDR AFTERLOADER LICENSEES ABOUT REPORTS CONCERNING ERRORS IN CATHETER RECONSTRUCTION DURING TREATMENTS.

ADDRESSEES

All medical licensees who utilize the Oncentra Brachy software program.

PURPOSE

The Arizona Radiation Regulatory Agency is issuing this information notice (IN) to inform Arizona licensees of the catheter reconstruction errors that have occurred while using the Oncentra Brachy software.

DISCUSSION

In January 2016, the following NRC Event Reports concerning errors in catheter reconstruct during HDR brachytherapy treatments were sent to the Complaint Handling Team located at the Principal Supply Center (PSC) in Veenendaal, Netherlands for evaluation. The reports were sent to explore if possible improvements to the Oncentra Brachy software could be made to enhance the usability and prevent the catheter reconstruction errors.

Please see the attached results of the investigation as well as an informational bulletin from the manufacturer.

CONCLUSION

The Agency is requesting that each licensee review their HDR program with regards to the Oncentra software package and evaluate if they have incorporated the bulletin into their Oncentra User Manual.

If there are any questions or concerns regarding this informational notice, please contact Brian Goretzki at 602-255-4840.