UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

July 7, 2015

EN 50982
NMED No. 150206 (Open)

Ms. Erika W. Wehrmeister
Chief Operating Officer
St. Vincent Hospital & Health Care Center
2001 West 86th Street
Indianapolis, IN 46260

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001579/2015001(DNMS) –
ST. VINCENT HOSPITAL & HEALTH CARE CENTER

Dear Ms. Wehrmeister:

On April 20, 2015, through April 21, 2015, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your hospital in Indianapolis, Indiana. The inspection included continued in-office review through June 12, 2015. The purpose of the inspection was to review the circumstances, causes, and corrective actions pertaining to an event that St. Vincent Hospital & Health Care Center reported to the NRC as a medical event on April 13, 2015. The event involved a high dose-rate brachytherapy treatment using iridium-192 that occurred on April 13, 2015. The in-office review included a review of your written followup report on the event and discussions with representatives from the device manufacturer and NRC staff from NRC Headquarters and the NRC's Region I office. Ms. Deborah A. Piskura of my staff conducted a final exit meeting by telephone with you, Mr. Edward Wroblewski, and other members of your staff on June 12, 2015, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

During this inspection, the NRC did not identify any violations of NRC requirements. As discussed with you on June 12, 2015, the NRC is continuing to evaluate two unresolved items identified during this inspection: (1) the probable causes of the damaged check cables and any potential generic implications, and (2) the licensee's performance of daily obstruction tests and any potential generic implications. The details of these two unresolved items are discussed in the enclosed inspection report. The results of the NRC's evaluation of these two unresolved items will be provided to you by separate correspondence.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.

Please feel free to contact Deborah A. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

Patrick L. Louden, Director
Division of Nuclear Materials Safety

Docket No. 030-01579
License No. 13-00133-02

Enclosure:
IR 03001579/2015001(DNMS)

cc w/encl: Edward E. Wroblewski, M.A., Radiation Safety Officer
Thomas Schmidt, M.D., Referring Physician
State of Indiana

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Thomas Schmidt, M.D., Referring Physician
State of Indiana

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Letter to Erika Wehrmeister from Patrick L. Louden dated July 7, 2015.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001579/2015001(DNMS) – ST. VINCENT HOSPITAL & HEALTH CARE CENTER

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01579
License No.	13-00133-02
Report No.	03001579/2015001(DNMS)
NMED No.	150206 (Open)
Licensee:	St. Vincent Hospital & Health Care Center
Facility:	2001 West 86th Street Indianapolis, Indiana 46260
Inspection Dates:	April 20 through 21, 2015, with continued in-office review through June 12, 2015
Exit Meeting Date:	June 12, 2015
Inspectors:	Deborah A. Piskura, Senior Health Physicist Luis A. Nieves Folch, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

St. Vincent Hospital & Health Care Center
NRC Reactive Inspection Report 03001579/2015001(DNMS)

Two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on April 20, 2015, through 21, 2015, to review the events and circumstances associated with a medical event that St. Vincent Hospital & Health Care Center (the licensee) reported to the NRC on April 13, 2015.

On April 13, 2015, the licensee administered a patient treatment for breast cancer using its high dose-rate remote (HDR) afterloader with an eleven channel SAVI® applicator. The authorized user prescribed a dose of 3,400 centiGray (cGy) (3,400 rad) in ten fractions at 340 cGy (340 rad) per fraction. As part of the licensee's daily safety checks, the authorized medical physicist performed an "obstruction" test to check the device's safety features when the unit encounters a constricted or blocked catheter. During the first treatment fraction, as the HDR unit proceeded with its test run of the check cable for the third channel, the computer console indicated a "friction error" message and a "source failed to retract" message with numerous audible alarms. The licensee staff implemented its emergency procedures and removed the patient from the treatment room. The licensee manually retracted the check cable into the HDR unit. After performing additional tests of its safety checks, the licensee staff observed that the check cable was jammed within the HDR unit; the licensee terminated the patient treatment.

Based on the licensee's calculations, the patient received a dose of approximately 60 cGy (60 rad) – equivalent to 60 rem – or 18 percent of the prescribed fractioned dose to the treatment site. The administered fractioned dose differed from the prescribed fractioned dose by more than 50 rem to an organ or tissue, and the fractionated dose delivered differed from the prescribed dose by 50 percent. The licensee determined that this treatment met the criteria for an NRC medical event, as defined in Title 10 of the *Code of Federal Regulations* (CFR) Part 35.2, and reported the event to the NRC Headquarters Operations Center on April 13, 2015. The licensee concluded that the medical event would not result in adverse health consequences for the patient.

A medical event occurred as a result of damage to the HDR check cable. Visual examination of the check cable found that the cable was frayed approximately one centimeter behind the welded junction. The damage to the check cable prevented the licensee from operating its HDR unit and completing the patient's treatment fraction on April 13, 2015. The licensee informed the inspectors that it experienced a previous issue with a check cable on November 7, 2014, however, this issue was discovered during a routine maintenance service call and did not affect a patient treatment. On May 29, 2015, the licensee informed the NRC of a third occurrence involving damage to the check cable (installed following the April 13, 2015, medical event) that was discovered during a routine source exchange. At the time of issuance of this report, the factors that could have contributed to these multiple occurrences involving damage to the HDR check cables was still under review.

No violations of NRC requirements were identified during this inspection. The inspectors identified two unresolved items concerning multiple occurrences involving damage to the HDR check cables and the performance of obstruction tests on the HDR unit. The resolution of these issues will be communicated to the licensee following completion of the NRC's evaluation.

REPORT DETAILS

1 Program Overview and Inspection History

NRC License Number 13-00133-02 authorizes St. Vincent Hospital & Health Center (the licensee) to use byproduct material at 16 locations of use for diagnostic and therapeutic nuclear medicine, and iridium-192 in an Elekta, Inc. (formerly Nucletron) Model 106.990 HDR unit for brachytherapy treatments. The licensee is authorized to administer HDR treatments at two locations; the majority of the licensee's use is at its main hospital in Indianapolis, Indiana. The licensee typically performed 850+ HDR treatments annually for breast and gynecological cancers. The licensee upgraded its HDR unit in August 2014. The licensee used the services of a contract medical group to staff its radiation oncology department with six authorized users and four authorized medical physicists. The authorized medical physicists operated the controls to the HDR unit. The licensee established a service agreement with the HDR unit vendor for quarterly source exchanges, periodic service, and annual preventative maintenance. The vendor provided training to the staff on the emergency procedures at least annually.

A routine safety inspection was initiated on September 16 through 19, 2013, with continued in-office review through October 8, 2013. One violation of NRC requirements was identified involving use of licensed material by a qualified but unauthorized physician user who was not listed on the license as an authorized user in License Condition 12.B. This licensee-identified and corrected violation was dispositioned as a Non-Cited Violation consistent with Section 2.3.3 of the NRC Enforcement Policy. No violations were identified during the previous inspection conducted on July 23, 2012, conducted to review the licensee's corrective actions for a violation involving an unauthorized physician user.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors reviewed the licensee's investigation of the medical event. The inspectors also interviewed selected licensee personnel, and observed related equipment and facilities.

2.2 Observations and Findings

A 74 year old female patient was prescribed an HDR treatment to the right breast utilizing an eleven channel SAVI® applicator. The authorized user prescribed the total dose of 3,400 cGy (3,400 rad) to be delivered in ten fractions, two fractions per day, for five days. On April 13, 2015, the licensee staff prepared to treat the scheduled patients, including the first fraction for this patient, for the day and performed the routine morning safety checks as well as quality assurance checks on the HDR unit without incident. These daily checks serve to ensure that the treatment room and the HDR unit satisfy the requirements in 10 CFR 35.615. The licensee documented its daily checks on a form. One of these checks included an "obstruction" test where the staff connected a bent lung catheter, approximately 11 centimeters in length, into the HDR unit head and ran a test to mimic an obstruction within the treatment catheter. The objective of this test was to ensure that in the event of a kink or blockage within the treatment catheter, the source

will retract into the shielded safe. Although the results of the obstruction test are not noted on the licensee's "HDR Unit Morning QA Form," the test is recorded in the HDR computer. This obstruction test is not required by NRC regulations or the conditions of an NRC license.

At approximately 8:40 a.m. EDT, on April 13, 2015, the licensee staff initiated the first treatment fraction for the patient. The licensee staff observed that the HDR unit console indicated that the check cable tests and the treatments for channels 1 and 2 progressed without incident. As the HDR unit proceeded with its test run of the check cable for channel 3, the computer console indicated a "friction error" message and a "source failed to retract" message with numerous audible alarms. The authorized medical physicist pressed the emergency stop button on the console to halt the treatment. The authorized medical physicist noted that the audible alarms continued to sound; however, the treatment room area radiation monitor was not flashing and the radiation indicator above the treatment room door was not illuminated. The authorized medical physicist entered the treatment room with a survey meter and surveyed the patient and the HDR unit, observing background levels of radiation. The authorized medical physicist attempted to manually retract the source back into the HDR unit shield and noted that the hand crank would not turn. The authorized medical physicist concluded that the HDR source must be secured within the shield safe. The authorized medical physicist disconnected channel 3 within the applicator from the HDR unit and observed a portion of the wiring (later determined to be the check cable) protruding approximately two centimeters from the channel head. The authorized medical physicist surveyed this wiring and observed no radiation readings. Using the hand crank for the check cable, the authorized medical physicist manually retracted the check cable into the unit. The staff disconnected all treatment catheters from the patient and escorted her to the waiting room.

The authorized medical physicist repeated the routine morning safety checks and the quality assurance checks using single channel source positioning jig and observed no error codes. He again performed the safety tests with a SAVI® applicator and observed the "friction error" code on the HDR computer, as experienced during the patient's treatment in channel 3. Once the authorized medical physicist disconnected the treatment catheter from the HDR unit, he observed a portion of the check cable protruding from the HDR head. Attempts to manually return the check cable to the stored position by using the hand crank were unsuccessful. The authorized user aborted any further patient treatment until the unit could be serviced by the vendor.

The licensee contacted the vendor who dispatched a field service engineer to the hospital on April 14, 2015. Examination of the check cable found that it was frayed with one strand of wire unraveled from the braided cable and separated, breaking off and leaving a small tail of wire. The fray/break was located approximately 0.5 centimeters behind the welded junction (see Attachment 1). The field service engineer replaced the damaged check cable.

On April 14, 2015, the licensee resumed treating patients with the unit, including the patient involved in the medical event. The remaining treatment course for this patient was completed without incident. The licensee added a day of treatment to compensate for their inability to complete the first fraction on April 13, 2015, due to the check cable damage. Based on the licensee's calculations, the patient received a dose of approximately 60 cGy (60 rad) – equivalent to 60 rem – or 18 percent of the prescribed

fractioned dose to the treatment site. The administered fractioned dose differed from the prescribed fractioned dose by more than 50 rem to an organ or tissue, and the fractionated dose delivered differed from the prescribed dose by 50 percent. The licensee determined that this treatment met the criteria for an NRC medical event, as defined in 10 CFR Section 35.2, and reported the event to the NRC Headquarters Operations Center on April 13, 2015. The licensee anticipated no adverse effects to the patient as a result of the medical event.

During the reactive inspection, the licensee revealed that there was a prior instance of a damaged check cable. A field service engineer discovered damage to the check cable during a routine source exchange on November 7, 2014. The field service engineer identified damage to the check cable at a small area located approximately 0.5 centimeters behind the welded junction. Upon visual examination, the cable was characterized as "bulging" and frayed. The licensee provided a photograph of this damaged cable to the inspectors (see Attachment 2). The field service engineer replaced this damaged check cable.

On May 28, 2015, during a routine source exchange, the licensee provided both damaged check cables referenced above to the field service engineer for transfer to the device manufacturer for evaluation. During this source exchange, the licensee requested the field service engineer to examine the recently replaced check cable in its HDR unit. On May 29, 2015, the licensee contacted the Region III office informing the NRC of another damaged check cable. The licensee described this cable as "compromised" and bulging at approximately 0.5 centimeters from the welded junction (see Attachment 3). The vendor replaced this cable on June 1, 2015. One unresolved issue was identified involving these multiple instances of damage to the HDR unit check cable.

2.3 Conclusions

A medical event occurred as a result of an event involving a jammed the HDR check cable. The damaged check cable lodged within the HDR unit and prevented the licensee from completing the treatment fraction. The licensee terminated the treatment fraction once it recognized the error code for a friction error. The licensee experienced an issue with a check cable on November 7, 2014, however this issue was discovered during a service call not a patient treatment. In addition, the check cable recently installed in the HDR unit following the medical event was observed to be damaged. It is unknown what factors could have contributed to these observations involving damage to the HDR check cables. The evaluations of the check cable failures were still under review at the time of publication of this report. The NRC was continuing its review of this issue and any potential generic implications related to it. This issue is considered an unresolved item.

3 Notifications and Reports

3.1 Inspection Scope

The inspectors reviewed the licensee's notifications to the NRC Headquarters Operations Center, the referring physician, and the patient. In addition, the inspectors

reviewed the licensee's written report describing the medical event and the damaged check cable.

3.2 Observations and Findings

On April 13, 2015, the day of the administration, the licensee notified the NRC Headquarters Operations Center of the medical event (Event Number 50982). The licensee notified the patient and the patient's referring physician. In addition, the licensee provided the referring physician and the patient a copy to its written report on the medical event. The licensee provided its written report of the medical event to the NRC in a report received on April 28, 2015, detailing its corrective actions. The report included the information required by 10 CFR 35.3045(d)(1).

3.3 Conclusions

The licensee made all of the notifications and reports as required by 10 CFR Part 35 within the required timeframes. The licensee's written reports included all of the required information.

4 Obstruction Tests on the HDR Unit

4.1 Inspection Scope

The inspectors reviewed the licensee's procedures for performing daily "obstruction" tests for its HDR units. The inspectors also interviewed selected licensee personnel and observed related equipment and facilities.

4.2 Observations and Findings

As part of the daily safety checks performed in accordance with 10 CFR 35.615, the licensee staff included an "obstruction" test. At the main hospital, this obstruction test consists of connecting a bent lung catheter, approximately 11 centimeters in length, into the HDR unit head and exposing the check cable to travel to the bent end to mimic an obstruction within the treatment catheter. The objective of this test was to ensure that in the event of a kink or blockage within the treatment catheter, the source will retract into the shielded safe within the HDR unit. The licensee's satellite hospital in Anderson, Indiana, also performed an obstruction test but used a lung catheter coiled around a plastic pipe as the test method.

The licensee provided a photograph of the jig used at the main hospital in the daily obstruction test (see Attachment 4). The licensee staff stated that this method of performing the daily obstruction test has been in place since their tenure. The licensee staff could not provide an explanation how this test originated or who designed this jig. The jig consisted of a lumen catheter fastened to a connector which seats in the HDR unit channel. The catheter is approximately 11 centimeters in length with the distal end bent backwards and taped. The results of this obstruction test are recorded in the HDR treatment computer.

According to the authorized medical physicists, the licensee had been performing this obstruction test for approximately several years. Until November 2014, the licensee was

not aware of any occurrences involving damage to the HDR check cable at its facility. The inspectors reviewed the licensee's application for license renewal and other supporting documents and noted that there were no license commitments or requirements for the hospital to perform this obstruction test. Discussions with the device manufacturer revealed that no recommendations or instructions were provided to the licensee for performing an obstruction test. The licensee described how an obstruction test was performed at its HDR clinic in Anderson, Indiana.

4.3 Conclusions

The manner in which the licensee performed its daily obstruction tests is under continued review by the NRC. It is unknown whether or not the daily obstruction test had any impact on the check cable. The NRC is continuing its review of this issue and any potential generic implications related to it. This issue is considered an unresolved item.

5 Licensee Corrective Actions

5.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions to prevent similar events. The review included the licensee's written report received on April 28, 2015, regarding the medical event. The inspectors also interviewed selected licensee personnel.

5.2 Observations and Findings

The licensee took immediate remedial actions which included administering an additional HDR treatment fraction to the patient. The licensee investigated the root cause of the medical event and its procedures for performing obstruction tests on its HDR unit. The licensee attributed the cause of the medical event to the damaged HDR check cable. It is unknown if the obstruction test contributed to the damaged check cable or the medical event. Following the medical event, the licensee revised its procedure to performing an obstruction test. On April 24, 2015, the licensee adopted the procedure used by its Anderson, Indiana clinic, which involved coiling a lumen catheter around a pipe. The licensee had been conducting an obstruction test using this revised method for approximately five weeks when it reported a third occurrence of a damaged check cable on May 29, 2015.

During a teleconference on June 2, 2015, the Radiation Safety Officer informed the inspectors that the hospital elected to cease performing an obstruction test on its HDR units. The licensee stated that it would visually examine the check cable at biweekly intervals for any indications of damage.

5.3 Conclusions

The inspectors determined that the licensee implemented adequate corrective actions to address the medical event.

6 Other Areas Inspected

6.1 Inspection Scope

The inspectors reviewed other aspects of the licensee's radiation protection program, which included, security of licensed material, personnel monitoring, training, labeling of containers, and postings. The inspectors interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers and reviewed selected records.

6.2 Observations and Findings

The inspectors observed three HDR brachytherapy treatment administrations. The inspectors reviewed the respective written directives and the treatment plans and interviewed the attending authorized users and the medical physicists. The inspection included observations of quality assurance checks, safety checks, security of byproduct material, use of personnel monitoring, and patient surveys.

The inspectors examined the HDR treatment unit and noted it to bear a clearly visible label identifying the source, radionuclide, and source activity. The inspectors observed that the licensee posted a copy of NRC Form 3. The inspectors also observed that the areas where licensed material was used and stored were appropriately locked and posted with "CAUTION-RADIOACTIVE MATERIALS" signs. The HDR treatment console area was also posted with emergency procedures and contacts. The inspectors performed radiation surveys around HDR unit and the treatment room and noted no radiation levels in excess of regulatory limits. The licensee staff involved with HDR treatments attended annual in-services with practice sessions on the emergency procedures.

6.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspectors identified no violations of NRC requirements in the areas inspected.

7 Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on April 21, 2015. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented. The final exit meeting was subsequently conducted via telephone on June 12, 2015, and included a discussion of the licensee's actions taken in response to the multiple occurrences of damaged HDR check cables.

LIST OF PERSONNEL CONTACTED

*H. Robin Conners, BSN, JD, CPHQ, Director, Accreditation & Patient Safety
*#Earl Dietrich, M.S., Chief Medical Physicist, Authorized Medical Physicist
Thomas C. Dugan, M.D., Radiation Oncologist
*#Faud Hammoudeh, FACHE, Executive Director, Cancer Care
Frank W. Peyton, Jr., M.D., Radiation Oncologist
*#Kristine Terrill, RN, BSN, Director, Radiation Oncology Services
*#Travis Charles Webb, M.S., Authorized Medical Physicist
*Erika Wehrmeister, Chief Operating Officer
*#Edward E. Wroblewski, M.A., Radiation Safety Officer

Debra Bensen, Radiation Safety Officer, Elekta, Inc.
Dennis Tressler, Field Service Engineer, Elekta, Inc.

*Chuck Callahan, Biomed Modality Manager, TriMedx

*Attended exit meeting on April 21, 2015
#Participated in the telephonic exit meeting on June 12, 2015

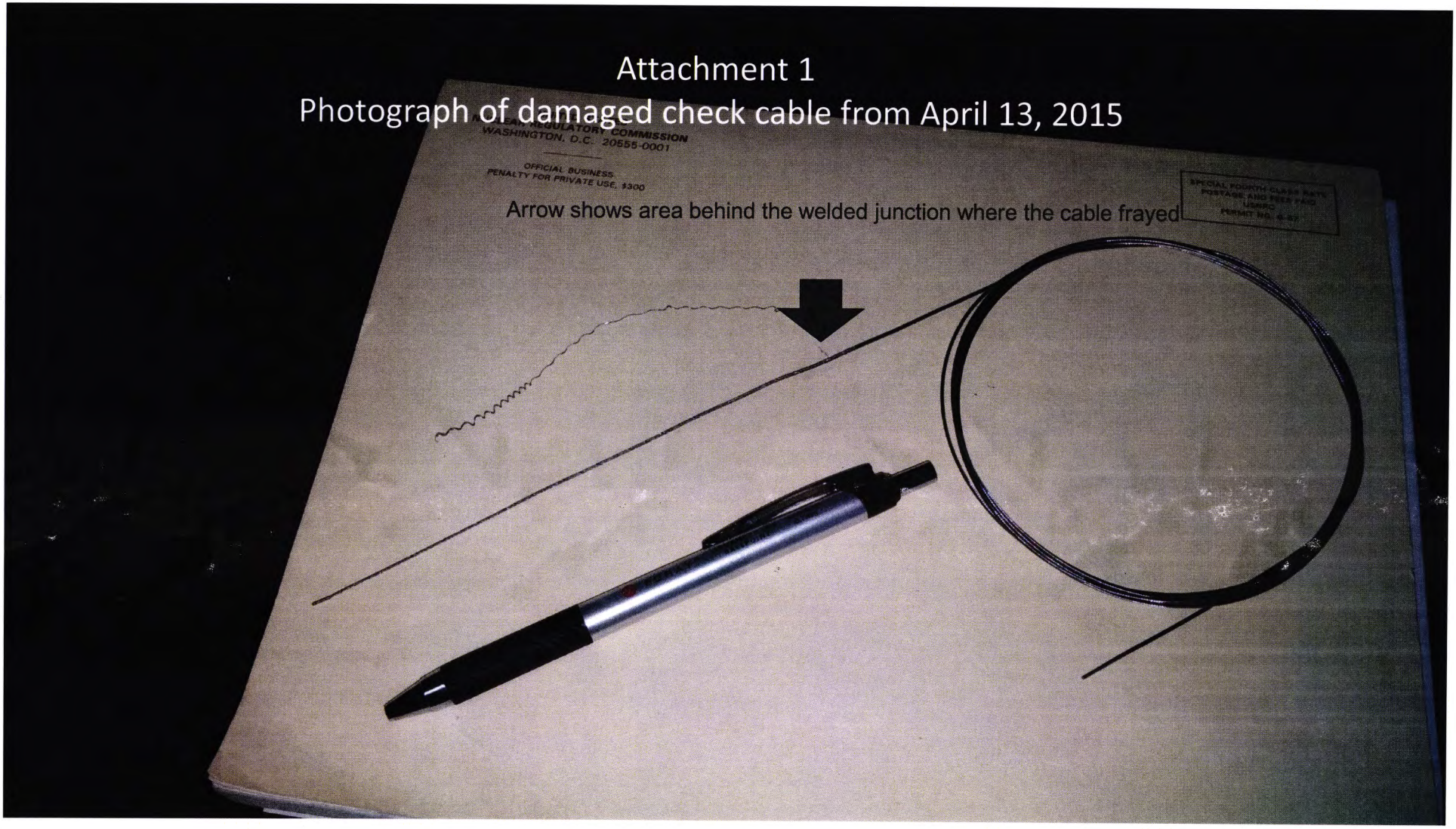
INSPECTION PROCEDURES (IP) USED

IP 87103, “Inspection of a Materials Licensee Involved in an Incident or Bankruptcy”
IP 87132, “Brachytherapy Programs”

ATTACHMENT: SUPPLEMENTAL INFORMATION

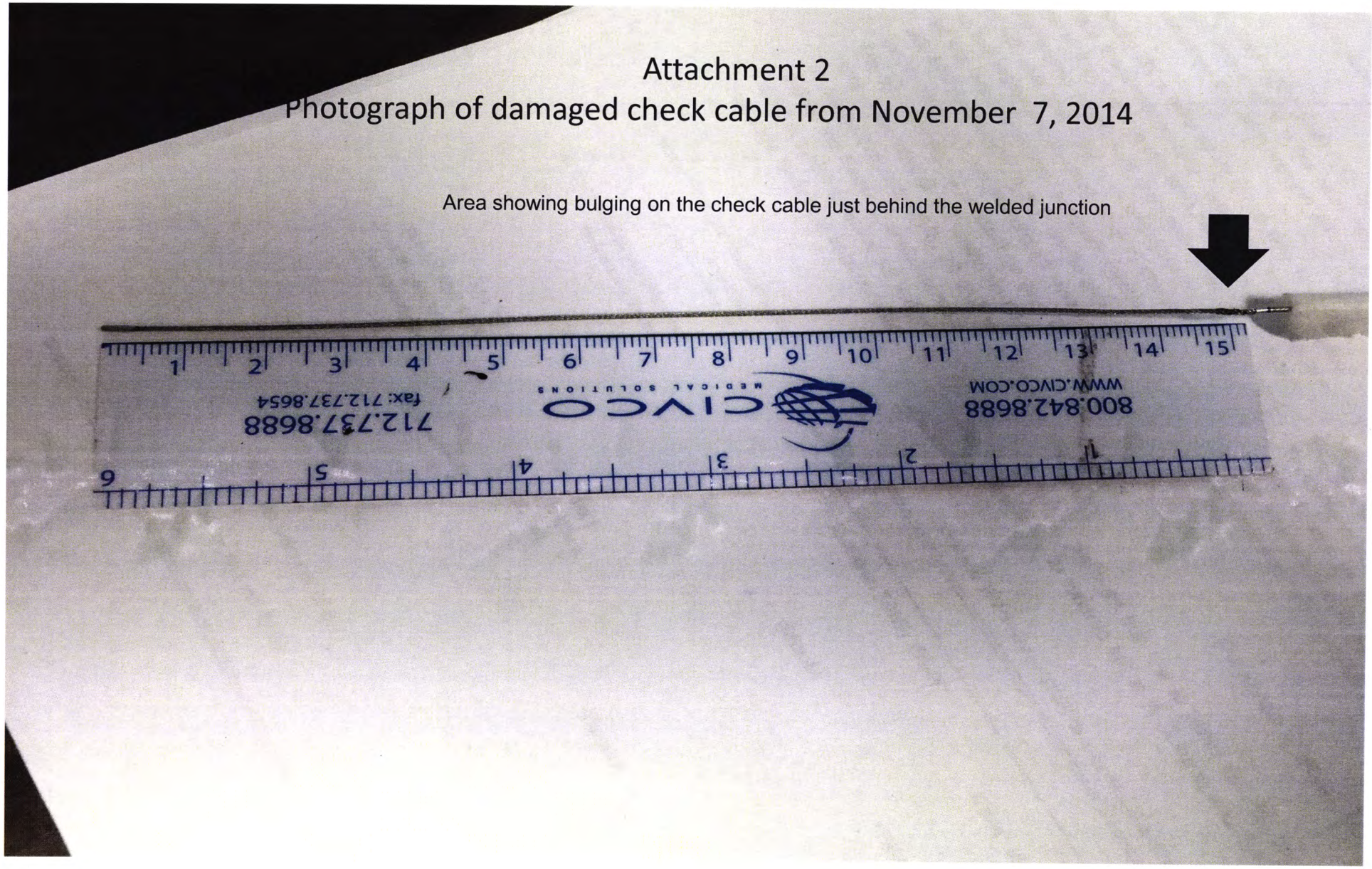
Attachment 1

Photograph of damaged check cable from April 13, 2015

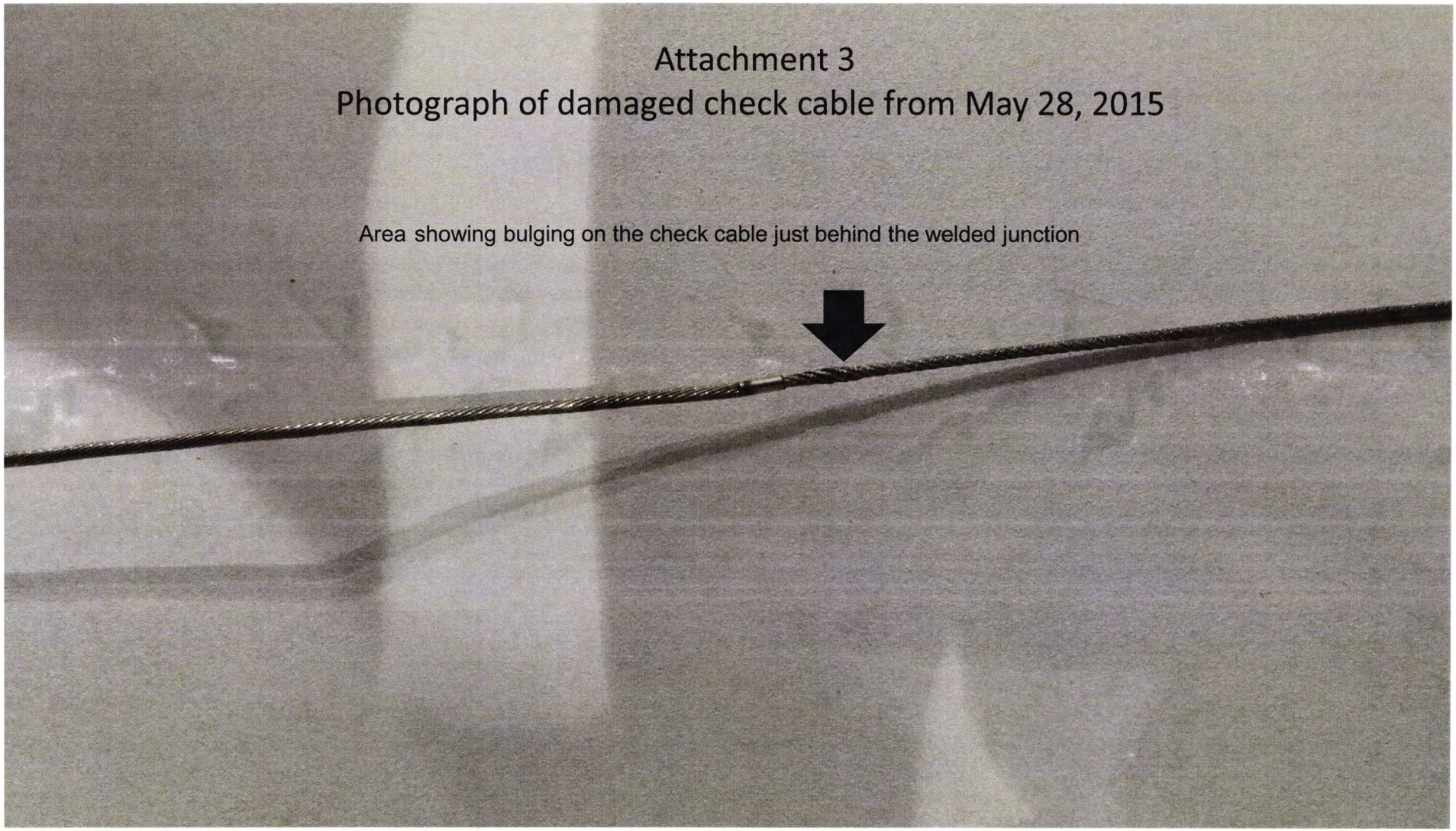


Attachment 2
Photograph of damaged check cable from November 7, 2014

Area showing bulging on the check cable just behind the welded junction



Attachment 3
Photograph of damaged check cable from May 28, 2015



Attachment 4
Jig used to conduct daily “obstruction” test