



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

February 5, 2021

EN 54706
NMED 200221 (No change to event closure status)

Ms. Marisol Sanchez
Vice President of Legal Affairs, General Counsel
Endress+Hauser, Inc.
2350 Endress Place
Greenwood, IN 46143

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03037942/2020001(DNMS)
ENDRESS+HAUSER, INC.

Dear Ms. Sanchez:

From August 26, 2020, through January 13, 2021, an inspector and additional staff from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection involving your facility in Greenwood, Indiana. The purpose of the inspection was to review information and activities surrounding the reported failure (EN 54706) of a generally-licensed Model FQG61 fixed gauge at the INEOS Oligomers Chocolate Bayou facility in Alvin, Texas, that was distributed by Endress+Hauser, Inc. Because the failure occurred in Texas, an Agreement State, the State performed the onsite follow-up to the damaged gauge and the possible exposure to radiation of several individuals. The NRC inspection reviewed the event to determine whether the gauge's Sealed Source and Device Registration (SSDR) certification, which was issued by the NRC, or the gauge's licensing basis, which is included in the NRC license issued to Endress+Hauser, needed to be revised to address any potential generic safety problem with the Model FQG61 gauge. The enclosed inspection report presents the results of the NRC inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. 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 observations of the operation of a representative intact gauge; a review of selected procedures and representative records, including the reports you provided on the evaluations of the body of the gauge from Texas performed by Endress+Hauser at your facilities in Greenwood, Indiana, and Maulburg, Germany; an examination by the NRC in person and via a video link of the body of the gauge from Texas at your Indiana facility; and interviews with personnel.

Based on the results of this inspection, no violation was identified concerning the SSDR certification or the licensing basis of this device and no generic safety problem was identified. Dr. David Alley and Mr. Tomas Herrera of the NRC's Office of Nuclear Materials Safety and Safeguards, Messrs. David Pelton and Geoffrey Warren of NRC's Region III office, and I discussed these findings with you and Mr. Benjamin Scher of your staff at the inspection exit

meeting on January 13, 2021. You are not required to respond to this letter or the enclosed report unless you disagree with the information or positions described therein. In this case, or if you choose to respond, clearly mark your response as "Reply to IR 03037942/2020001(DNMS)" and send it to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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>. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Warren of my staff if you have any questions regarding this inspection. Mr. Warren can be reached at Geoffrey.Warren@NRC.gov or 630-829-9742.

Sincerely,

Michael Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-37942
License No. 13-32721-01

Enclosure:
IR No. 03037942/2020001(DNMS)

cc w/encl: Benjamin Scher, Radiation Safety
Officer
State of Indiana
State of Texas

Letter to Marisol Sanchez from Michael Kunowski, dated February 5, 2021.

SUBJECT: NRC INSPECTION REPORT NO. 03037942/2020001(DNMS)
ENDRESS+HAUSER, INC.

DISTRIBUTION w/encl:

- Jack Giessner
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- Linda Howell
- Randy Erickson
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NAME	GWarren:ps		DAley		MKunowski			
DATE	1/26/2021		2/1/2021		2/5/2021			

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**U.S. Nuclear Regulatory Commission
Region III**

Docket No. 030-37942

License No. 13-32721-01

Report No. 03037942/2020001(DNMS)

EN / NMED No. 54706 / 200221

Licensee: Endress+Hauser, Inc.

Facility: 2350 Endress Place
Greenwood, Indiana

Inspection Dates: August 26, 2020 – January 13, 2021

Exit Meeting Date: January 13, 2021

Inspector: Geoffrey Warren, Senior Health Physicist, Materials
Inspection Branch, Region III

Other NRC Staff: David Alley, Ph.D., Branch Chief, Materials Safety
and Tribal Liaison Branch (MSTB) in the Office of
Nuclear Material Safety and Safeguards (NMSS)

Tomas Herrera, Team Leader, MSTB, NMSS

Michael Kunowski, Branch Chief, Materials
Inspection Branch, Region III

Approved By: Michael Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Endress+Hauser, Inc. NRC Inspection Report 03037942/2020001(DNMS)

A reactive inspection was conducted by the NRC to review the possible generic issues following the failure on June 30, 2020 (EN 54706), of a fixed gauge at a chemical plant in Texas, an Agreement State. The gauge, a generally-licensed Endress+Hauser Model FQG61 gauge, contained a 95-millicurie cesium-137 sealed source. The inspection focused on the Sealed Source and Device Registry (SSDR) certification and the licensing basis for this model gauge to determine if revision of the certification or the distribution license for the gauge was needed. The certification and license were both issued by the NRC. No generic issues or violations of NRC requirements were identified during the inspection. The NRC staff concluded that the failure of the gauge, in which the rotary element containing the source separated from the gauge body, may have resulted from an application of an excessive, unknown external force to the rotary element.

In support of the onsite review of the event by the State of Texas, NRC made an upper-bounding dose calculation for plant personnel who may have been exposed to the source. These calculations indicated the possible whole-body dose was well below an initial estimate that it could exceed 25 rem.

REPORT DETAILS

1 Program Overview and Inspection History

Endress+Hauser, Inc. (licensee) is authorized under NRC Materials License No. 13-32721-01 to distribute both specifically- and generally-licensed fixed gauges to facilities in the United States. These gauges are imported complete and in their shipping crates from Germany to the licensee's facility in Greenwood, Indiana. In addition, the licensee maintains gauges for training and demonstration purposes at the Greenwood facility. The Model FQG61 fixed gauge that is the subject of this inspection was approved for use as a generally-licensed gauge by the NRC in Sealed Source and Device Registry (SSDR) certification NR-1302-D-101-B.

No violations were identified during the licensee's last two routine inspections, performed January 27, 2015, and September 26, 2019.

2 Distribution and Registration of Generally-Licensed Device

2.1 Inspection Scope

The inspector and other NRC staff reviewed the operation, distribution, and registration of the generally-licensed Model FQG61 fixed gauge through observing selected activities with a similar gauge; interviewing licensee staff; reviewing documentation concerning an event involving a particular Model FQG61 gauge that occurred at the INEOS Oligomers Chocolate Bayou facility in Alvin, Texas; and participating in in-person and video examination of the gauge body when it arrived at the Greenwood facility from the facility in Texas. The purpose of this inspection was to determine whether this event indicated a generic issue with the Model FQG61 gauge due to a quality control or design deficiency; the specific review of the event at the facility in Texas and the possible resulting exposures are under the jurisdiction of the State of Texas, an Agreement State.

2.2 Observations and Findings

In October 2019, a generally-licensed Model FQG61 fixed gauge containing a 95-millicurie cesium-137 source was installed at the INEOS Oligomers Chocolate Bayou facility, a chemical plant in Alvin, Texas. On June 30, 2020, the gauge failed when the gauge's rotary element came out of the gauge body and the sealed source came out of the source tube in the rotary element, resulting in the unintended possible exposure of two workers to the unshielded source (EN 54706). This failure was preceded by the separate failures of the two arms welded to the rotary element of the gauge. NRC Region III instituted a reactive inspection to evaluate the distribution and registration of the gauge based on Endress+Hauser, Inc., the gauge distributor, being a licensee of the NRC.

In support of Region III's reactive inspection of the licensee, the Materials Safety and Tribal Liaison Branch (MSTB) in the Office of Nuclear Material Safety and Safeguards, the branch that conducts reviews as part of the SSDR certification process, performed an evaluation of this event. In its review, MSTB considered its own assessment of photographs provided of the gauge at various points during the time period leading to the source separating from the source tube; information provided from the gauge user; information provided by the State of Texas; and failure analyses conducted at the

licensee's U.S. distribution and service facility in Greenwood, Indiana, and the licensee's manufacturing facility in Maulburg, Germany. Due to the loss of the rotary element in transit between the gauge user in Texas and the Greenwood facility, the failure analyses were limited to the gauge body – less than ideal but sufficient to assess the likely cause of the separation of the rotary element, containing the source, from the gauge body. Based on all available information, the MSTB staff concluded that the separation of the rotary element from the gauge may have been the result of damage to the gauge as a result of the application of an excessive, unknown, external force. This conclusion is consistent with the evaluations performed by the licensee that indicated the appearance of damage due to external forces. The NRC was unable to conclude why the two arms on the rotary element failed and why the source came out of the rotary element once the rotary element had separated from the gauge body. The gauge design includes a screwed, pivoting circular cover that normally retains the source within the source tube in the rotary element. Photographs of the gauge at the Texas facility show the cover installed on the rotary element. Removal of the rotary element containing a source and pivoting of the cover to allow access to the source are activities that only Endress+Hauser representatives or other specifically-licensed persons are allowed to perform.

In addition to the analysis described above, MSTB staff searched the Nuclear Materials Events Database to determine whether similar events were reported. No other events were found in the United States involving this model of gauge or similar devices. The licensee reported that they had distributed 169 FQG61 gauges in the United States since 2010 as well as an additional 5726 gauges worldwide and had not been informed of a similar gauge failure event. As a result, MSTB staff have concluded that the event at the facility in Texas appears to be unique at this time and that the FQG61 devices can continue to be used. Based on available information there do not appear to be any generic implications involving the gauges; however, staff will continue to monitor event notifications for similar events.

State of Texas personnel have performed a review of the event and the resulting exposures. No adverse health effects were observed in any of the seven individuals that the facility concluded might have been exposed to the Cs-137 source. The NRC has performed dose modeling using a number of programs in support of the State of Texas inspection; this modeling and the lack of adverse health effects support the State's determination that no exposure exceeded the Abnormal Occurrence (AO) reporting criterion of an event that may have resulted in a total effective dose equivalent to an individual of 25 rem or more. Abnormal Occurrences are events or conditions which the NRC must report to the U. S. Congress. Potential AOs are selected using the AO criteria published in the *Federal Register* on October 2, 2017, (82 FR 45907), available at <https://www.federalregister.gov/documents/2017/10/02/2017-21043/abnormal-occurrence-reports>.

2.3 Conclusions

Based on the results of this inspection, no violation was identified concerning the certification or distribution of this device. In addition, the NRC identified no concerns that would indicate a need to revise the registration of the device or the licensing of the distribution of the device.

3 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on January 13, 2021. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

LIST OF LICENSEE PERSONNEL CONTACTED

- # Marisol Sanchez, Vice President of Legal Affairs, General Counsel
- # Benjamin Scher, Radiation Safety Officer

- # Attended exit meeting on January 13, 2021

INSPECTION PROCEDURES USED

- IP 87103 Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
- IP 87124 Fixed and Portable Gauge Programs
- IP 87125 Materials Processor/Manufacturer Programs