ITT ENGINEERED VALVES

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2nd Interim Report to the NRC of
10 CFR 21 Event 50285, reported by ITT 07/18/14
Concerning M1 diaphragms, Customer Testing

REPORT BY: Stephen T. Donohue 4/7/15

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1.0 INTRODUCTION

ITT Engineered Valves, LLC (ITT) was obligated to point out to end users a potential defect with items considered Basic Components for Nuclear industry service, on July 18, 2014. This notification took the form of a formal 10 CFR Part 21 Notice, which became Event #50285. The component items in question are ITT's M1 EPDM Diaphragms, which were sold as parts incorporated into valve assemblies or as individual spare parts since the initial release of this M1 diaphragm compound in 2008, and also certain ITT items (ball valve seats and diaphragms) that were qualified via special projects for specific customer applications. The "potential defect" applies to affected items that are intended for Nuclear radiation applications. The problem came to light as a result of an NRC investigation of Steris Isomedix Services (Steris). The NRC found that Steris did not properly account for variances in radiation that could occur depending on where samples were placed in Steris' irradiation chamber. Based on this finding and also ITT's subsequent evaluation of the matter, ITT has concluded that there may be as much as 10% unaccounted uncertainty in the specified radiation dosage called for by ITT during Steris' treatment of samples that were used to qualify ITT's products. Any such affected component that was sold or is being sold will need to be evaluated as to the effect of the uncertainty in the test results on the actual component in service. As this evaluation can only be made by the customer after reviewing the usage and application of the affected item, this defect is best characterized as 'potential' by ITT.

Initial notification of the potential defect was made to the NRC via fax on 7/18/14. The potential defect report was designated Event 50285 shortly thereafter. A 30-day Written Notification was filed with the NRC on 8/15/14 and is available on the NRC web site. A 60-day Interim Report was failed on 9/17/14 and is also available on the NRC web site.

Per 10 CFR part 21 requirements, this report is another Interim Report. The report is 'Interim' and not 'Final' because ITT is not able to close out the Nonconformances; due to the fact that the application and time of exposure comes into play in service, the determination of the impact of the potential defect is a responsibility that can only be borne by the end user.

2.0 POTENTIAL IMPACT OF NONCONFORMANCE

(Note: this section is a repeat of section 4.0 in the 30-day Written Notification report)

M1 Diaphragms

When the current EPDM M1 diaphragm compound was initially qualified during 2007 – 2008, samples of each size were manufactured and delivered to ITT's R&D lab. After conducting the standard qualification testing of unradiated diaphragms, samples were prepared for life cycle testing of irradiated samples. This consisted of sending samples to Steris for irradiation, retrieving and then testing the sample diaphragms at specific temperatures and pressures based on past customer requirements, ASME Code Case N31, MSS SP-100 testing, etc.

ITT used Steris to apply radiation to these diaphragm samples. Due to issues with variability in applied radiation levels as discovered by the NRC during the inspection at Steris conducted in May, 2014 (NRC inspection report #99901445), and as a result of ITT's review of that inspection report, ITT has determined that the minimum level of radiation specified by ITT for the M1 qualification project may not have been applied to the samples per ITT's stated minimum requirements. Due to this uncertainty in applied radiation level, it is possible that the actual dosage applied was as much as 10% lower than the minimum specified by ITT.

This 10% uncertainty was an accumulation of two issues:

1. Location in irradiation chamber – As a result of the NRC Notice of Nonconformance, Steris notified ITT in its June 18, 2014 letter that there was more uncertainty associated with the actual radiation dosage applied than was previously considered. The variation that now had to be accounted for was due to irregularities in measurement and sample placement in the radiation chamber. Followup correspondence from Steris indicated that ITT should have accounted for an additional +/- 3.5% uncertainty when specifying minimum radiation levels for M1 samples.
2. Dosimeter uncertainty - In ITT's purchase orders during the M1 qualification project in 2008, it was specified to Steris that certain levels of radiation should be applied to our samples, with a specified minimum value required. A statement that Steris' dosimeters carried a +/- 6.5% uncertainty was listed in the quotation paperwork, and also included on the certificate of conformance document. Since ITT specified that a minimum level be

applied, it was not at all clear that by referencing the 6.5% uncertainty Steris was indicating that ITT had to then account for the dosimeter uncertainty by adjusting our targeted "minimum" desired radiation value accordingly. It was not until reviewing the NRC Nonconformance report 99901445 that it was recognized that ITT's 2008 qualification should have accounted for a 6.5% dosimeter uncertainty.

Customer Projects

Since 2008 there have been three projects that were initiated by ITT customers that required the use of irradiation application services from Steris. Such projects would come about when a customer needed ITT products to meet a specific customer condition that was not previously validated. In these cases a special test project was initiated in order to qualify ITT products for a given application, and the project required irradiated samples for qualification. These projects had results that could have been affected by both the off-carrier location uncertainty and the dosimeter variation uncertainty. ITT is able to identify these customers and inform them of the Event, see below.

3.0 END USER COMMUNICATION

ITT directly contacted all M1 diaphragm customers via formal letter in late July - early August. Spurred by this and the NRC notifications, many end users followed up with ITT with more questions and requests for more information. Direct correspondence was received from the end users and other interested parties; a partial list is shown below:

Wolf Creek Nuclear Operating Corp.
AEP, Cook Nuclear Plant
PSEG
NRC, Northeast Region
Ameren
South Carolina Energy and Gas (SCEG), VC Summer
Nuclear Utility Group on Equipment Qualification (NUGEQ)
Entergy, Indian Point
Duke Power, Oconee and also Headquarters
Exelon, Byron and Braidwood
Luminant, Comanche Peak

PG&E, Diablo Canyon
Southern Co., Vogtle
TVA, Watts Barr Nuclear
Entergy, Waterford 3
APS, Palo Verde
New Brunswick Power, Point Lepreau
Dominion Power
Exelon, Three Mile Island
Dominion Power, Surry
.... as well as many others....

All customer inquiries regarding the 10 CFR part 21 event have been fully addressed by ITT (usually within the same day), and inquiries continue to be handled as quickly as possible. Ongoing sales of ITT M1 diaphragms from the compound that has been in use since 2008 are accompanied by a letter notifying end users of the 10 CFR 21situation.

Customers who purchased special services from ITT in order to conduct testing and qualification of irradiated components (diaphragms or ball valve seats) since 2008 are listed below. ITT has informed each of the three customers about the nonconformance and is addressing the issue per the customer's instructions, as follows:

1. Duke Energy Corporation (Oconee), PO 00151156
   Due to minimum radiation limits imposed by Steris, the diaphragm samples that were tested had an applied radiation dosage that was so high that even with a 10% reduction, the amount of radiation actually seen by the qualification samples far exceeded the customer's requirements for this project. No action required.
2. Exelon Generation Company (Braidwood and Byron), PO 636683-01
   The Customer asked ITT to revise the test reports to indicate the effective radiation dosage that was actually applied to the qualification samples, accounting for the uncertainties in the radiation process that were found after the fact. Revised reports have been submitted to the Customer.
3. Luminant Generation Company (Comanche Peak), PO 0731098 6D2
   Customer has been informed of the fact that the radiation dosages for this testing should effectively be reduced by 10%. ITT is awaiting further instructions regarding possible test report changes.

In February, ITT sent out an announcement to all end users that the EPDM compound used to make M1 diaphragms since 2008 is no longer viable, and that a

new EPDM compound for M1 diaphragms has been developed and is now available. See Appendix A. As far as Event 50285 is concerned, the new M1 was qualified using samples that were fully radiated to account for all known uncertainties. Therefore, the new M1 diaphragms can replace any diaphragms that may have been deemed suspect according to the 50285 Event, provided that the new M1 performance has been verified for the applicable condition. See Section 5 below.

4.0 MITIGATION EFFORTS

ITT has had some success in mitigating the effects of this 10 CFR part 21 Event with certain customers with M1 diaphragms in service, by reviewing their applications in detail. It has been found in some cases that the radiation requirements of a customer's particular application were such that the Event had no effect on that customer's M1 diaphragms. If the radiation requirements in the governing specification for a given valve in service are much less than the applicable qualification test radiation level, then the diaphragm can still be considered "qualified" and there is no need to replace any diaphragms in service. ITT's qualification of the M1 diaphragm was not nullified by the results of Event 50285. Irradiated diaphragms were still qualified to a given operating pressure and temperature, and the test results are still valid although at a 10% reduction in effective radiation. But even with that 10% reduction, the effective radiation level of ITT's qualification test samples has been found to be much greater than the radiation requirements of many valves in certain services. End users are encouraged to contact ITT to see if this same situation could apply to their diaphragms.

5.0 DIAPHRAGM REPLACEMENT STATUS

In previous correspondence regarding this 10 CFR part 21 Event, ITT had committed to releasing for sale M1 diaphragms that have been qualified for all customer applications using irradiated samples that accounted for all known uncertainties that were brought to light by Event 50285. The release of the appropriately qualified diaphragms was to begin in December 2014 and carry through to 1st quarter 2015. This has been achieved, for the most part: eight of nine sizes of M1 diaphragms have been released to production, and five of these

are available for immediate sale at this time: ½", ¾", 1", 2" and 2.5". Stock quantities of 1.5", 4" and 6" sizes are currently being arranged and scheduled.

One size – 3" - is not released for production at this time. The 3" size has suffered some technical setbacks and will require more time to develop and release. Tentative release date of this size is set at May 1, 2015.

Please note that ITT's approach to providing appropriately qualified diaphragms has been to qualify a brand new M1 EPDM compound. The current M1 compound that was originally released in 2008 was not re-qualified to radiation dosages that would account for all known uncertainties, for two reasons:
1) The existing EPDM compound that has been used to make M1 diaphragms sold by ITT since 2008 has become obsolete, as the base polymer is no longer being manufactured and is no longer available to ITT. Furthermore, there are not enough remaining diaphragms from this compound to perform an appropriate qualification that would cover all potential customer conditions.
2) The new M1 compound was already in development and in the process of being qualified when the 10 CFR 21 Event occurred, so the fastest path to release of appropriately radiated M1 product was to proceed with the ongoing qualification of the new compound.

The forced obsolescence of the current M1 compound and subsequent development and release of the new M1 compound is a recent occurrence, and an announcement letter was sent out to all ITT customers in mid-February. See Appendix A.

All of the new M1 diaphragms were qualified using irradiated samples that were appropriately prepared with the minimum applied radiation dosage necessary to account for all known uncertainties. The known uncertainty factor is 10%, so the minimum required target dosages for samples were increased by 10% to account for the uncertainty.

Due to the differences in results between the old M1 and the new M1 compound, summary data documents are being prepared for each size. These summary documents are also intended to help satisfy 'no substitution allowed' documentation requirements that are in place for many end users. Appendix B of this report shows what one of these summary documents looks like, and is for the new 1" M1 diaphragm.

It is noted that for some sizes and conditions, the performance of the new M1 diaphragm in irradiated testing differs from the 2008 formulation (for non-radiated service, the new M1 is equivalent or better in every way than the old M1). ITT conducts a variety of irradiation qualification tests intended to cover as many end user applications as possible. For some sizes, the new M1 was able to meet or exceed the performance of the old M1 in every single irradiated test condition. However, for other sizes there were certain conditions for which the new M1 performance fell short of what the old M1 was able to attain. To a certain extent this is expected due to the fact that the samples used to qualify the new M1 diaphragms were exposed to 10% more radiation than the samples that were used to qualify the old M1 back in 2008, and this increase in radiation is significant. Where the new M1 could not meet the old M1, or in cases where the new M1 was not able to attain the full five year qualification cycle life of 7,500 cycles, the lowest attained number of cycles is shown, and this number is used to calculate a modified yearly cycle limit, or an effective total number of cycles with a safety factor of 3, for that size/condition.

Please note that these summary documents are intended to verify whether the end user *Operating* pressures and temperatures are satisfied by the radiated qualification test results. ITT performs qualification testing of irradiated diaphragms within the operating pressure and temperature regime; the intent of the testing is to demonstrate that the function of the valve (opening and shutoff) can be maintained during an operational service life with simulated radiation exposure. The radiation test results as shown in the summary documents do not apply to *Design* pressure and temperature limits, as those higher conditions govern the structural integrity of the entire valve and do not apply to the shutoff performance.

6.0 INTERIM REPORT SUMMARY

On 7/18/14, ITT reported a potential 'failure to comply' defect to the NRC which involved the qualification of M1 diaphragms for radiated service, and also the qualification of select ITT products to specific customer-paid test programs. The qualification of these products had been conducted using samples that were radiated to minimum levels that did not completely account for all uncertainty in the measurement of the radiation applied, which was discovered after the fact. This uncertainty of appropriate supporting data was evaluated at ITT and deemed to be a potential cause of a substantial safety hazard per 10 CFR part 21.

ITT has communicated to all customers the particulars of this 10 CFR Part 21 potential defect, in the form of formal letters to each M1 diaphragm customer regarding existing product, letters included with all ongoing sales of M1 diaphragms, and direct contact with customers who purchased products qualified via customer directed testing. ITT continues to provide information to concerned customers when called upon, in order to aid their evaluation of the impact of the qualification uncertainty on products in service.

In order to further mitigate concerns ITT embarked on a new M1 diaphragm qualification project, repeating the qualification testing previously conducted in 2008 using appropriately irradiated diaphragms, which accounted for all applicable uncertainties in the radiation level measurement. This effort has been successful, and diaphragms from a new M1 compound are now in production in all sizes except 3". Please note that the appropriately qualified M1 diaphragms are from a new EPDM compound, as the compound that has been used since 2008 is obsolete.

While the new M1 diaphragm compound has been qualified using appropriately irradiated diaphragm samples, there were some conditions of certain sizes for which the performance of the new compound falls short of what was attained with the old compound. The reverse is also true, as the performance of the new M1 in some sizes/conditions actually improved. To assist end users in verifying that a given diaphragm will now meet a given customer requirement, a summary data sheets showing qualification results for many common customer operating conditions will be provided for every size of new M1 diaphragm.

ITT

ENGINEERED FOR LIFE

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February 16, 2015

(Utility Name)
(Utility Street Address)
(Utility City, State, Zip)
(Attention)

Subject: General Announcement Letter regarding M1 Diaphragm – New Compound

ITT is in the process of molding production quantities of M1 diaphragms made from a new formulation. These diaphragms, whose part numbers are shown in the table below, will replace M1 diaphragms made from the current formulation which has been in place since 2008. While ITT still has a limited quantity of the current M1 diaphragm in stock, one of the primary ingredients of the current M1 formulation has become obsolete, and it is no longer possible to mold M1 diaphragms from that material.

The performance of the new M1 formulation in general exceeds the performance of the current M1 in most sizes. However, due to the recent 10 CFR part 21 event #50285 (see details on NRC web site), it was necessary to account for greater uncertainties in the irradiation process during qualification such that the sample diaphragms used to qualify the new formulation were subjected to irradiation levels that were 10% greater than the irradiation that had been applied to 2008 formulation samples. This is a significant amount of radiation to overcome, and while the overall performance of the sample diaphragms indicates that the new M1compound is superior to the current, there were some conditions and sizes for which the new compound was not able to attain the same performance.

The table below shows the availability of the new diaphragms:

Size	Current M1 P/N	New M1 P/N	New M1 Inventory Status
1/2"	44681	47959	Released - In stock 4/1/15
3/4"	44680	47960	Released - In stock 3/6/15
1"	44673	47961	Released - In stock 3/2/15
1.5"	44674	47962	Not yet released
2"	45557	47963	Released - In stock 3/6/15
2.5"	44676	47964	Released - In stock 4/1/15
3"	44677	47965	Not yet released
4"	44678	47966	Not yet released
6"	45558	47967	Released - In stock 4/1/15

At this writing there is still a limited amount of current M1 diaphragms available in all sizes. As quantities deplete and sizes run out, ITT will make available summary documents that will show the performance comparison of the new compound versus the current for each size and condition.

10 CFR Part 21 event #50285

For those customers who have been waiting for replacements for M1 diaphragms that are considered to be compromised per the 10 CFR Part 21 event #50285: the new M1 diaphragms have been qualified using radiation dosages that properly accounted for all recently discovered uncertainties. The minimum applied radiation dosage was increased by 10% to account for Steris' final understanding of the uncertainties within their radiation process. While the majority of sizes of the new M1 can be considered a like-for-like substitution for the current M1 diaphragms, there are some conditions and sizes where the new M1 falls short of the performance of the current M1. Summary documents for each size will be made available to assist in confirming the service life of replacement M1 diaphragms.

Due to the fact that the previous M1 compound is no longer available and qualification samples cannot be produced, there will not be a re-qualification project for the current M1 diaphragms to account for the recently discovered uncertainty in the radiation process.

As noted in the table, most but not all of the sizes are released and available. This is in accordance with the latest Interim report that ITT filed on the NRC web site 09/17/14, the summary of which states: ITT will have all sizes of new M1 diaphragms released to production by the end of first quarter 2015.

Regards,

S.T. Donohue

S. T. Donohue
Sr. Principal Engineer

1" M1 EPDM Operating Conditions – New Compound

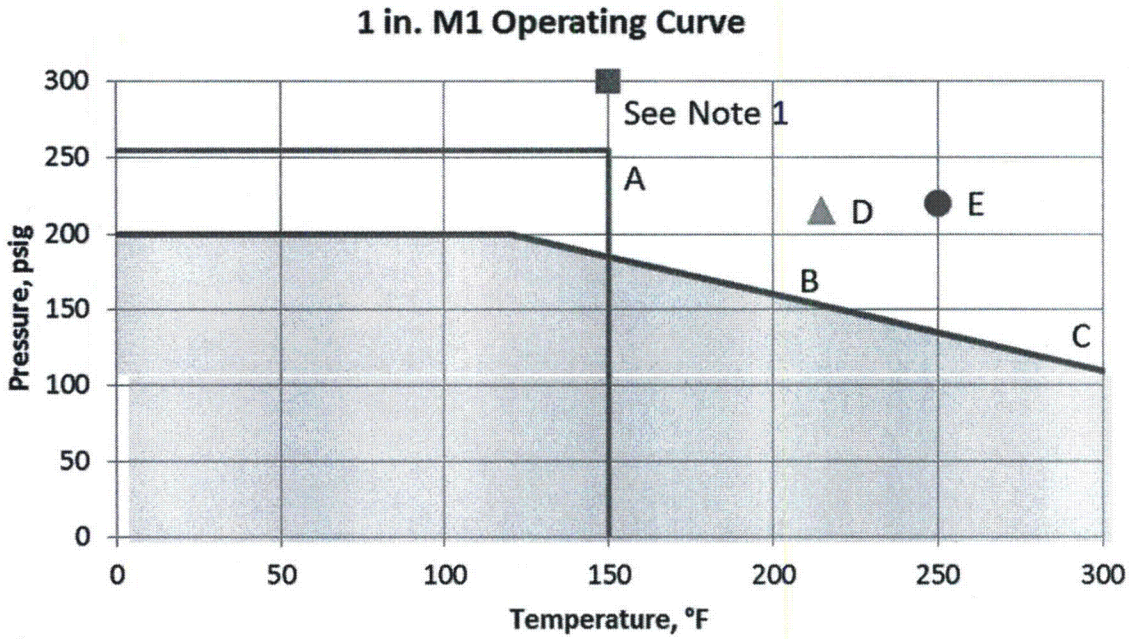
ITT is in the process of releasing a new compound for the M1 diaphragms. This document specifies the technical information and supporting data necessary to enable the user to justify the substitution of the new M1 diaphragm, similar to the Operating Conditions letter of 7/31/08 that governed the previous M1 compound.

As with the last compound, ITT's qualification testing is based on:

- 5 year accumulated radiation dose of 7.5 Mrads (based on 40 year dose of 100 Mrads, with 40% shielding)
- Target completion of 7,500 cycles (= 5 x 500 x 3), where
  - 5 year service life
  - 500 cycles per year
  - Safety Factor of 3
- All known uncertainties regarding irradiation of test samples were properly accounted for in minimum applied sample diaphragm dose.

OLD P/N	NEW P/N
44673	**47961**

N-31 CODE CASE CONDITIONS



NOTE 1: New 1" M1 is also approved for 150° F @ 300 psig, 1.2 Mrads (based on 40 year dose of 16 Mrads with 40% shielding) (Same Note 1 condition as 07/31/08 letter)

Condition A 150° F, 255 psig (same as shown on 07/31/08 letter)

New 1" M1 fully qualified to 7,500 cycles

Other N-31 Code Case conditions

There are also several customer applications that were not part of the scope of the original 07/31/08 Operating Conditions letter, for which ITT has provided M1 diaphragms since 2008. These conditions are covered below. Conditions B through E reference the graph on the previous page.

Condition B, C 200° F, 160 psig and 300° F, 110 psig (Commercial P/T curve)

New 1" M1 fully qualified to 7,500 cycles for both conditions above

Condition D 215° F, 215 psig (qualifies both 200° F at 215 psi, and 215° F at 200 psig conditions)

New 1" M1 fully qualified to 7,500 cycles, and exceeded performance of 44673 at this condition.

Condition E 250° F, 220 psig

Was not able to fully qualify new 1" M1 to 7,500 cycles
However, exceeded performance of old 1" M1 p/n 44673 at this condition.
Did qualify to 4,065 cycles, which translates to
Yearly service life of 271 cycles/year, with SF=3, five year service life
OR
Total service life of 1,355 cycles (4,065 with applied safety factor of 3)

MSS SP-100 condition

Additionally, ITT will test to the MSS-SP-100 protocols listed below:
(Based on 40 year dose of 1.6E8 Rads and 40% shielding) (also covered in 07/31/08 letter)

		Status
1"	170 psig @ 130° F, 1.2E7 Rads (5 year)	(ITT has not yet performed 1" MSS SP-100 test.)

1" M1 SUMMARY

The new 1" M1 p/n 47961 has been successfully qualified as equivalent or better than the previous 1" M1 p/n 44673 for all of the conditions covered on the 7/31/08 Operating Conditions letter (except for the MSS SP-100 test, which has not yet been completed). In addition, the new 1" M1 has proven to be equivalent or better for all customer operating conditions that were not originally part of the 7/31/08 letter but are now included here (conditions B through E above).