January 2021

Nuclear Material Events Database

Annual Report

Fiscal Year 2020

Prepared for the U.S. Nuclear Regulatory Commission
by Idaho National Laboratory (INL/LTD-20-60684)

INL/LTD-20-60684

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Published January 2021

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Prepared for the
U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Under U.S. Department of Energy-Idaho Operations Office
Contract DE-AC07-05ID14517

ABSTRACT

This report presents information on trending and analysis of incidents/accidents (events) reported to the Nuclear Regulatory Commission (NRC) that involve radioactive material. The events are reported by NRC licensees, Agreement States, and non-licensees, and are recorded in the NRC's Nuclear Material Events Database. The reported events are classified into categories based on event reporting requirements defined in Title 10 of the Code of Federal Regulations. The categories in this report are (1) Lost/Abandoned/Stolen Material, (2) Medical, (3) Radiation Overexposure, (4) Release of Licensed Material or Contamination, (5) Leaking Sealed Source, (6) Equipment, (7) Transportation, and (8) Other.

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ACRONYMS

ALARA	as low as reasonably achievable
ALI	annual limit on intake
AO	abnormal occurrence
AU	authorized user
CFR	Code of Federal Regulations
CT	computed tomography
DDE	deep dose equivalent
DE	dose equivalent
DOT	Department of Transportation
EDE	effective dose equivalent
EQP	Equipment
EXP	Radiation Overexposure
GTCC	greater than class C
HLW	high level waste
IAEA	International Atomic Energy Agency
IEMA	Illinois Emergency Management Agency
INL	Idaho National Laboratory
IV	intravenous
IVB	intravascular brachytherapy
LAS	Lost/Abandoned/Stolen Material
LKS	Leaking Sealed Source
LS	least squares
MED	Medical
MRI	magnetic resonance imaging
NA	not applicable
NMED	Nuclear Material Events Database
NR	not recovered
NRC	Nuclear Regulatory Commission
OTH	Other
REAC/TS	Radiation Emergency Assistance Center/Training Site
RLM	Release of Licensed Material or Contamination
RSO	radiation safety officer
SDE	shallow dose equivalent

SNM	special nuclear material
SSE	error sum of squares
SSR	regression sum of squares
SST	total sum of squares
TDSHS	Texas Department of State Health Services
TEDE	total effective dose equivalent
TRS	Transportation
VAC	voltage alternating current
VDC	voltage direct current

EXECUTIVE SUMMARY

The Nuclear Regulatory Commission's (NRC) Nuclear Material Events Database (NMED) contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The reported events are classified based on reporting requirements defined by Title 10 of the Code of Federal Regulations. The event reports are evaluated to identify statistically significant trends and events of higher significance (referred to as significant events in this report).

The significant events that occurred in Fiscal Year 2020 are summarized below. Some of these events are considered potential Abnormal Occurrences (AOs) until they complete NRC's formal AO determination process and are reported in NUREG-0090, *Report to Congress on Abnormal Occurrences*. Note that a single event may be listed in more than one event type category.

Lost/Abandoned/Stolen Radioactive Sources/Material Events

Eight significant events occurred involving the loss of 15 Category 1-3 sources as defined by the International Atomic Energy Agency's *Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. One Category 1 source, twelve Category 2 sources, and two Category 3 sources were lost; all of which were recovered except the two Category 3 sources.

Regarding the eight significant events:

- One of the events involved the loss of a Category 1 source. In this event, a container of a bulk radioactive material lost during shipping. The material was recovered.
- Five of the events involved the loss of Category 2 sources. All of these sources (12 total) were radiography sources that were subsequently recovered. In the first event, a package of eight sources was delivered to the wrong location. The remaining four events involved sources contained within radiography exposure devices:
    - One device fell from the tailgate of a truck en route to a jobsite.
    - One device was in a truck that was impounded after a radiographer was arrested for driving while intoxicated.
    - One device was in a truck that a non-authorized user took possession of during a financial dispute.
    - One device was in a truck that was washed into a river.
- Two of the events involved the loss of Category 3 sources. In the first event, a brachytherapy source was lost during shipping. In the other event, a radiography exposure device fell from an oil platform into the Gulf of Mexico. Neither of these sources were recovered.

In addition to the eight events above, one other significant event occurred prior to FY20 that was recently added to NMED. In this event, a common carrier delivered a brachytherapy source to an incorrect location at a hospital. The source was taken to the correct location approximately four hours later.

Medical Events

Nine significant events occurred, all of which were classified as potential Abnormal Occurrences. Eight of these events involved doses delivered to unintended sites during a variety of treatments: high dose rate afterloader (2 events), microsphere (2 events), eye plaque, prostate seed implant, gamma knife, and intravascular. The last event involved an eye plaque treatment that delivered a dose greater than prescribed.

Radiation Overexposure Events

Two significant events occurred, both of which were classified as potential Abnormal Occurrences. The first event occurred while employees were performing temporary repairs to a fixed gauge. One employee

unknowingly picked up a radioactive source that fell from the gauge and gave it to another employee, who put it in his shirt pocket. In the other event, a radiography crew was overexposed while retracting a radiography source through a damaged guide tube.

Release of Licensed Material or Contamination Events

One significant event occurred. In this event, a hospital's hot laboratory and adjacent area were radioactively contaminated when an authorized user intentionally broke open two I-131 capsules. The intent was to pour the contents into water to more easily administer the dose to a patient.

Leaking Sealed Source Events

No significant events occurred.

Equipment Events

Three significant events occurred. The first event occurred while employees were performing temporary repairs to a fixed gauge. One employee unknowingly picked up a radioactive source that fell from the gauge and gave it to another employee, who put it in his shirt pocket. In the second event, a radiography crew was overexposed while retracting a radiography source through a damaged guide tube. Both of these events were classified as potential Abnormal Occurrences. A third event involved an explosive chemical reaction inside a production hot cell during a rubidium dissolution process.

Transportation Events

Two significant events occurred, both of which involved packages shipped via common carrier that arrived with higher than expected radiation levels. The first package contained a radiography exposure device whose source had become partially unshielded during shipping. The second package contained a nuclear gauge.

Other Events

One significant event occurred, which was also classified as a potential Abnormal Occurrence. In this event, an embryo/fetus received a radiation dose when a patient who was unknowingly pregnant received an Lu-177 dotatate therapy treatment.

Nuclear Material Events Database Annual Report: Fiscal Year 2020

1. INTRODUCTION

1.1 Overview and Objectives

Nuclear material event reports are evaluated to identify statistically significant trends and significant events. The reported information aids in understanding why the events occurred and in identifying any actions necessary to improve the effectiveness of the nuclear material regulatory program.

A database for tracking nuclear material events was developed by the Nuclear Regulatory Commission (NRC) in 1981. In 1993, using existing material events databases, the NRC developed a new and more comprehensive database for tracking material events. This database, designated the Nuclear Material Events Database (NMED), contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The database is maintained by Idaho National Laboratory (INL) and contains approximately 26,000 records of material events submitted to the NRC from January 1990 to present.

The events in this report are classified into the following categories based on event reporting requirements defined by Title 10 of the Code of Federal Regulations (CFR):

- Lost/Abandoned/Stolen Material (LAS),
- Medical (MED),
- Radiation Overexposure (EXP),
- Release of Licensed Material or Contamination (RLM),
- Leaking Sealed Source (LKS),
- Equipment (EQP),
- Transportation (TRS), and
- Other (OTH).

A description of categories addressed in this report and associated screening criteria are presented in Appendix A.

1.2 NMED Data

A single occurrence report may be captured in more than one NMED event category. For example, a report may describe a loss of licensed material that also resulted in a radiation overexposure. In such a case, both event categories are recorded in the NMED and identified by the same report number (referred to as an item number in the database).

The data presented in this report are limited to reportable events that occurred between October 1, 2010, and September 30, 2020. The data were downloaded from the NMED on November 27, 2020. Because the NMED is a dynamic database that is updated daily, variations in data may be encountered over time. Furthermore, even though many events were reported and entered in the database for operational experience purposes, only those events required to be reported by 10 CFR are addressed in this report.

This report displays annual trend data for each of the event categories for a 10-year period. A trend analysis was performed on each event category to identify the existence or absence of a statistically significant trend. If a statistically significant trend exists, the display indicates the direction and

approximate rate of change with a trend line. For the purposes of this report, a statistically significant trend exists if the analysis indicates that the computed fit and slope of a least squares linear model is valid at a 95% confidence level. A primer on the statistical methods employed in the trend analysis is presented in Appendix B.

Note that the trending methodology is not normalized; the trend only considers the number of reported events and does not directly account for external issues such as changes to regulatory requirements or changes in the number of licensees. For example, an increasing trend in the number of medical events could be caused by an increase in the number of medical procedures being performed. Likewise, an event type showing a decreasing trend for NRC licensees and an increasing trend for Agreement State licensees could be caused by States becoming Agreement States (resulting in fewer NRC licensees and more Agreement State licensees).

Reporting guidance for Agreement States is provided in the *Handbook on Nuclear Material Event Reporting in the Agreement States*. The handbook is an appendix to the NRC Office of Nuclear Material Safety and Safeguards procedure SA-300, *Reporting Material Events*. Access to NMED is available to the staff of NRC, Agreement State, and Federal agencies at http://nmed.inl.gov.

For assistance on searches or other questions, contact Robert Sun (nmednrc@nrc.gov, 301-415-3421).

2. ANALYSIS OF NMED DATA

Event reports submitted to the NRC involving nuclear material are reviewed, categorized, and entered into the NMED. Charts are provided to display trends in annual data for the most recent 10-year period (FY11-20).

2.1 All NMED Events

Figure 1 displays the annual number and trend of NMED events that occurred during the 10-year period. The trend analysis determined that the NRC-regulated events represent a statistically significant decreasing trend (indicated by the trend line). However, the Total events and Agreement State-regulated events do not represent statistically significant trends (indicated by the absence of trend lines).

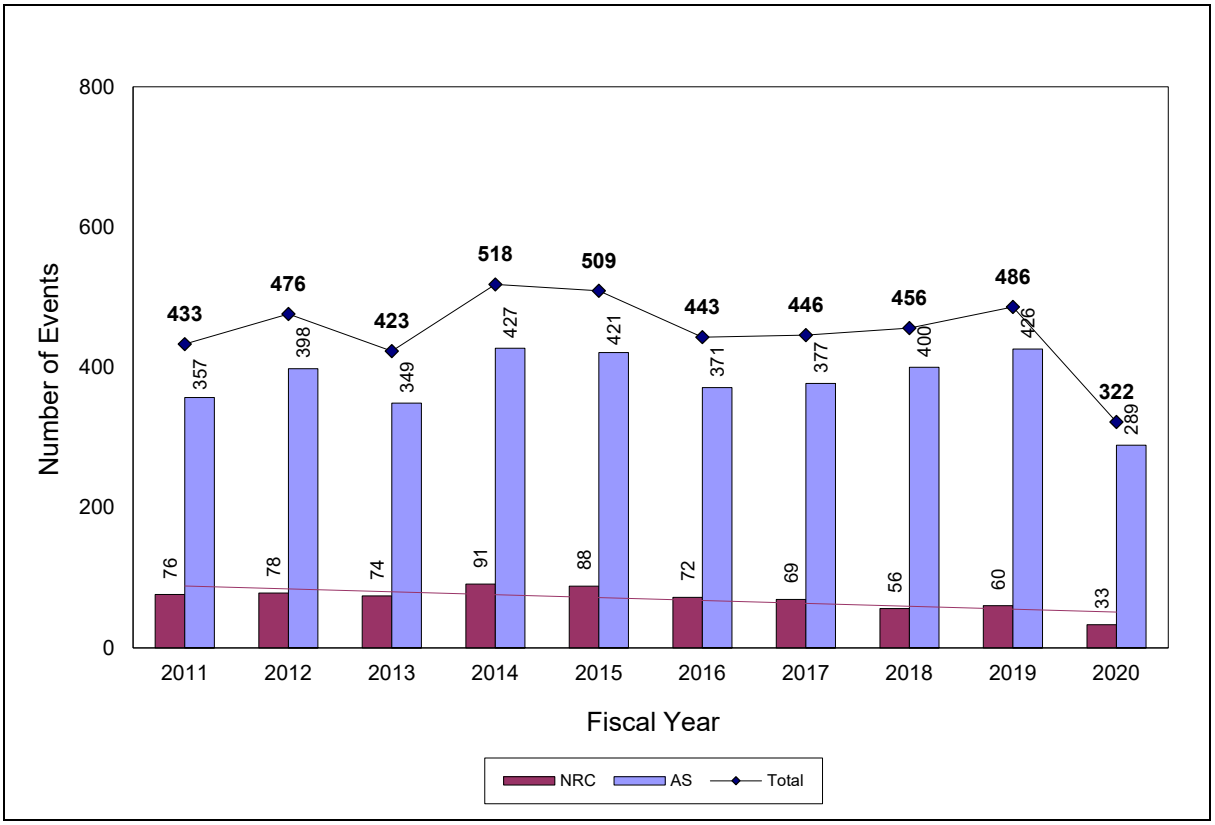

Figure 1. All NMED Events (4,512 total)

The following observations are made regarding the data in Figure 1.

- In FY20, 302 occurrences accounted for 322 events; a single occurrence can be classified in different event categories.
- The most recent year's data are typically many records less than their final value when subsequent updates and late reports are received (see Appendix D, Figure D-1).
- The transition of states from NRC to Agreement State jurisdiction could result in increasing trends in Agreement State data and decreasing trends in NRC data.

Table 1 displays a summary of the trending analysis for all NMED event types included in this report. A more detailed discussion of the trending analysis results can be found in the section of this report devoted to each event type.

Table 1. Summary of Trending Analysis

Event Type	Total	NRC	Agreement State
All NMED Events	-	↘	-
Lost/Abandoned/Stolen Material (LAS)	-	↘	-
Medical (MED)	-	-	-
Radiation Overexposure (EXP)	-	-	-
Release of Licensed Material or Contamination (RLM)	-	-	-
Leaking Sealed Source (LKS)	-	-	-
Equipment (EQP)	-	-	-
Transportation (TRS)	↘	↘	-
Other (OTH)	NA	NA	NA

Notes:

- ↗ indicates a statistically significant increasing trend.
- ↘ indicates a statistically significant decreasing trend.
- - indicates no statically significant trend.
- NA indicates that the data does not support trending analysis.

2.2 Lost/Abandoned/Stolen Material

2.2.1 Ten-Year Data

Figure 2 displays the annual number and trend of LAS events that occurred during the 10-year period. The trend analysis determined that the NRC-regulated events represent a statistically significant decreasing trend (indicated by the trend line). However, the Total events and Agreement State-regulated events do not represent statistically significant trends (indicated by the absence of trend lines).

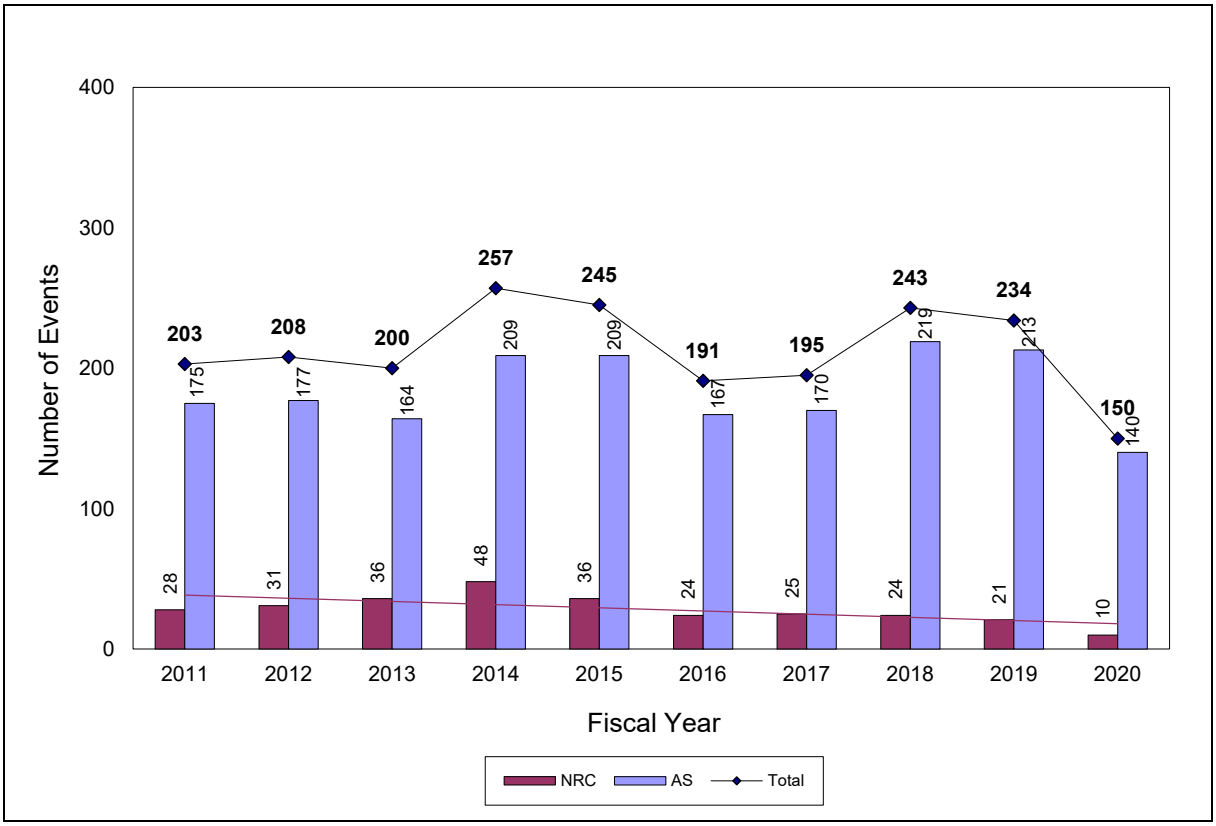

Figure 2. Lost/Abandoned/Stolen Material Events (2,126 total)

Appendix C contains a list of radionuclides derived from the International Atomic Energy Agency's (IAEA) *Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. These radionuclides are grouped by the amount of radioactivity into five categories that correspond to the relative hazard, with Category 1 being the most hazardous.

For this report, IAEA Category 1 through 3 source events (excluding irretrievable well-logging source events) are considered significant. Regardless of IAEA category, events involving irretrievable well-logging sources are not considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 2 displays the number of sources lost (approximately 3,832, excluding irretrievable well-logging sources) during the 10-year period and the number that have not been recovered (approximately 2,156), grouped by IAEA category where possible. These included three Category 1 sources, 68 Category 2 sources, and 39 Category 3 sources; all of which were recovered, with the exception of two Category 2 and six Category 3 sources.

Table 2. Number of Sources Lost/Abandoned/Stolen (LAS) and Sources Not Recovered (NR) - Excluding Irretrievable Well Logging Sources

Category		Fiscal Year 2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total
1	LAS[4]	0	0	0	0	2	0	0	0	0	1	**3**
	NR[5]	0	0	0	0	0	0	0	0	0	0	**0**
2	LAS	2	3	10	5	9	8	7	3	9	12	**68**
	NR	1	0	0	0	0	0	1	0	0	0	**2**
3	LAS	4	7	3	4	4	5	1	4	5	2	**39**
	NR	0	1	0	0	1	0	0	0	2	2	**6**
4	LAS	44	44	24	53	45	43	35	38	51	50	**427**
	NR	23	14	8	26	20	17	9	16	23	27	**183**
5	LAS	82	83	72	88	87	83	55	76	63	58	**747**
	NR	11	25	9	33	34	46	15	28	25	17	**243**
< 5	LAS	1	0	1	1	2	1	10	4	1	2	**23**
	NR	0	0	0	0	2	1	1	4	1	2	**11**
Activity Not Known[1]	LAS	12	9	7	3	3	1	1	3	3	9	**51**
	NR	0	0	0	0	1	0	0	0	0	0	**1**
Nuclide Not Known[2]	LAS	6	0	1	0	1	0	1	0	0	0	**9**
	NR	5	0	0	0	0	0	0	0	0	0	**5**
Other[3]	LAS	212	193	174	330	201	252	165	281	417	240	**2465**
	NR	141	132	92	257	110	187	75	173	322	216	**1705**
Total	**LAS**	**363**	**339**	**292**	**484**	**354**	**393**	**275**	**409**	**549**	**374**	**3832**
	NR	**181**	**172**	**109**	**316**	**168**	**251**	**101**	**221**	**373**	**264**	**2156**

Notes:

1. The "Activity Not Known" category includes sources containing radionuclides listed in Appendix C for which the activity was not reported. Therefore, the sources were not included in Categories 1 through 5.
2. The "Nuclide Not Known" category includes those sources for which the radionuclide was not reported. Thus, the sources were not included in Categories 1 through 5 or Other.
3. The "Other" category includes sources containing radionuclides not included in Appendix C.
4. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).

5. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The Category 1 through 3 "not recovered" source counts were corrected for the "partially recovered" source events.

Tables 3 and 4 provide more detail regarding the 10-year and current year "not-recovered" data highlighted in Table 2 in yellow and green, respectively. Table 3 displays radionuclide data pertaining to the IAEA Category 1 through 3 sources lost during the 10-year period that have not yet been recovered. The Decayed Activity values are conservative estimates in that the values are typically decayed from the loss date instead of the manufacturer's assay date. As a result, the actual decayed activities (based on the manufacturer's assay date) are likely less than the estimates. Table 4 is similar to Table 3 but limited to the current year.

Table 3. Summary of IAEA Category 1-3 Sources Not Recovered (FY11-20)

Radionuclide	Half-life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Total Decayed Activity IAEA Category
Ir-192	73.83 days	6	115.3	2.3	3
Pu-238	87.7 years	2	5.3	5.0	3
Total		**8**	**120.6**	**7.3**	**3**

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).
3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the "partially recovered" source events.
4. The source activities were decayed from the event date to 11/27/2020 (data download date).

Table 4. Summary of IAEA Category 1-3 Sources Not Recovered (FY20)

Radionuclide	Half-life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Total Decayed Activity IAEA Category
Ir-192	73.83 days	2	28.0	2.1	4
Total		**2**	**28.0**	**2.1**	**4**

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).
3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the "partially recovered" source events.

4. The source activities were decayed from the event date to 11/27/2020 (data download date).

2.2.2 FY20 Data

One hundred fifty LAS events occurred in FY20, two of which involved irretrievable well logging sources. Excluding the irretrievable well logging sources, approximately 374 sources were lost/abandoned/stolen, 264 of which have not been recovered. Of the 374 lost sources, one was Category 1, twelve were Category 2, and two were Category 3 sources; all of which were recovered except the two Category 3 sources.

Eight of the FY20 LAS events were considered significant (involved Category 1-3 sources). Note that regardless of IAEA category, events involving irretrievable well logging sources are not considered significant.

Significant Events - Category 1 Source Events

Item Number 200031 - A radioactive source manufacturer reported that a shipment of bulk radioactive material from an overseas supplier was not delivered as expected. The shipment contained six separate Type B containers, but only five were delivered. The sixth contained approximately 458.8 TBq (12,400 Ci) of Ir-192 and was not delivered. The shipment left Paris, France, on 1/8/2020 and arrived in Memphis, Tennessee, on 1/9/2020. The shipment was then supposed to move on to Boston, Massachusetts, over the weekend. The shipment was located by the common carrier in Memphis, Tennessee, on 1/14/2020. It was delivered to Burlington, Massachusetts, on 1/15/2020. The shipment was not damaged. The Massachusetts Radiation Control Program completed an investigation of the incident. The source manufacturer implemented a checklist to use during events to accurately make reports within the required time frame.

Significant Events - Category 2 Source Events

Item Number 200014 - A radioactive source manufacturer reported that a single package containing eight Ir-192 radiography sources, with a total activity of 32.72 TBq (884.2 Ci), was delivered to a hospital in Honolulu, Hawaii, on 12/30/2019, instead of the intended radiography equipment vendor in Edmonton, Canada. The hospital secured the package in a locked utility room overnight. On the morning of 12/31/2019, the hospital identified that the package was intended for Canada and immediately contacted the common carrier and source manufacturer. The common carrier retrieved the package on 1/2/2020 and delivered it to its intended destination on 1/6/2020. The NRC performed an inspection at the hospital on 1/15/2020 and determined that they took thorough and appropriate actions. The source manufacturer and the Commonwealth of Massachusetts investigated. This event was caused by a human performance error by the common carrier.

Item Number 200090 - A radiography services company reported a temporary loss of control of a radiography exposure device. On 3/1/2020, one of their technicians was sleeping in a radiography truck in a parking area. Local law enforcement arrived and arrested the technician for driving while intoxicated. At approximately 8:00 am, the technician called the site RSO and informed him of the situation. Law enforcement stayed with the technician until a tow truck arrived and impounded the vehicle at approximately 8:30 am. The vehicle was locked, the alarm on the dark room was activated, and the technician took all the keys to the dark room and radiography exposure device with him. The vehicle was carrying an exposure device containing a 2.96 GBq (80 Ci) Ir-192 source. Company personnel arrived at the impound yard at approximately 10:15 am and provided surveillance of the vehicle until it was released to them. They verified that the alarm system on the dark room was still armed and the exposure device was present. They returned the truck to the company's facility. The company terminated the offending technician's employment. All employees were required to complete additional training with regard to policy compliance.

Item Number 200170 - A radiography services company reported that a radiography exposure device was temporarily in the possession of a non-authorized user. One of the owners, who was not an authorized user, took possession of four of the company's radiography vehicles during a financial dispute. A

radiography exposure device containing a 3.26 TBq (88 Ci) Ir-192 source was in one of those vehicles. The exposure device was subsequently retrieved, verified not to have been tampered with, and placed back into storage on 4/6/2020. Corrective actions included changing the locks in the shop area and retraining staff on licensed material security requirements.

Item Number 200234 - A radiography services company reported the loss and recovery of a radiography exposure device containing a 1.739 TBq (47 Ci) Ir-192 source. A radiography crew was crossing a bridge southeast of Fredericksburg, Texas, on 5/28/2020 when their truck was washed into the river. The exposure device was secured in the truck, locked inside a robust overpack container, held by locked metal brackets, and bolted to the truck. Company staff responded to search for the truck, aided by county law enforcement with a helicopter. On 5/29/2020, the truck was found almost totally submerged one mile downstream from where it entered the river. The darkroom, which had separated from the truck, was found on 5/30/2020, approximately 9.9 miles downstream from where it entered the river. Both were recovered and held in Fredericksburg on 5/31/2020 for the insurance company to examine. The truck and darkroom were later transported to one of the radiography services company's facilities. Neither the exposure device nor the overpack were in the truck or darkroom. On 5/31/2020, the exposure device was found on the riverbank approximately 8.5 miles from where the truck entered the river. The device was still secured inside the overpack container. The device was sent to the manufacturer for inspection, repairs, and leak tests. The leak tests were negative. The device had no damage except for the lock assembly. The lock assembly was repaired and the identification and radioactive material side plates were replaced. Corrective actions included reviewing details of the incident with employees to improve awareness, developing an awareness process to inform employees of hazards and risks in unfamiliar locations, and reviewing internal programs regarding safe driving. This event was classified as an EQP and LAS event.

Item Number 200370 - A radiography services company reported the loss and recovery of a radiography exposure device containing a 1.41 TBq (38.1 Ci) Ir-192 source. On 9/9/2020, a radiography crew placed the exposure device on the tailgate of their truck at the company's facility and drove away without securing it. The device fell from the truck within a short distance (781 feet from the exit gate). A second crew left the facility approximately 10 minutes later and found the device on the pavement. The second crew performed a radiation survey of the device and found the radiation levels to be normal and the source still fully shielded. The second crew returned the device to the company's facility. The device was inspected and did not appear to be damaged. The company sent the device to the manufacturer for inspection. Corrective actions included terminating the employment of involved personnel, modifying procedures, and conducting safety training. The inspection report from the manufacturer indicated that the gauge was not damaged in the event.

Significant Events - Category 3 Source Events

Item Number 200063 - A radioactive source vendor reported the loss of a 369.52 GBq (9.987 Ci) Ir-192 high dose rate brachytherapy source. The source was being shipped to a medical center in Golden, Colorado. The source's last known location was a common carrier's shipping hub in Memphis, Tennessee. The State of Tennessee was notified on 2/7/2020.

Item Number 200094 - An oilfield services company reported the loss of a radiography exposure device that contained a 666 GBq (18 Ci) Ir-192 source. The device fell overboard while being moved between exposure locations on an offshore oil production platform in the Gulf of Mexico. The company did not attempt to retrieve the device. Corrective actions included personnel training and procedural changes.

Events of Interest

Item Number 200034 - A metal recycling facility reported finding a device containing a Ra-226 source at their metal scrap yard on 1/14/2020. The device had no markings or labels. There was no loose radioactive contamination detected. Maximum exposure rates on the device were 1,200 mR/hour on contact and 6 mR/hour at one meter. The device was secured at the facility pending disposal. The device

was believed to be a fixed nuclear gauge with a 925 MBq (25 mCi) Ra-226 source. The Ohio Department of Health attempted to identify the owner of the device but was not successful. The device was removed by a licensed waste broker on 3/24/2020.

Item Number 200078 - A construction materials testing company reported the theft and recovery of a moisture/density gauge that contained a 1.48 GBq (40 mCi) Am-Be source and a 0.37 GBq (10 mCi) Cs-137 source. The gauge was last seen on 2/19/2020 at the end of work in McKinney, Texas. It was locked in a box in the back of a truck that was driven to Euless, Texas, where it stayed until 2/24/2020. The truck was driven to a job site in Richardson, Texas, on 2/24/2020. At that point, the employee realized that the locks were missing and the gauge had been stolen. The Euless Police were notified. The Texas Department of State Health Services received a phone call on 6/17/2020 stating that a moisture/density gauge had been found in a load of scrap metal from a large recycling steel mill in Midlothian, Texas. The serial number identified this as the stolen gauge. The testing company was notified on 6/18/2020, retrieved the gauge, and transported it to one of the manufacturer's locations in Arlington, Texas, for disposal. The gauge had apparently been through a shredder and the outer casing was gone. The identification tags were in place on the shielding, though there was some damage. The Am-Be source was in its shielded position. The Cs-137 source rod had broken off and the rod, with the source still attached to the end, was separated from the shielding. The Cs-137 source did not appear to be damaged or compromised. After the Cs-137 source was inserted into the shield, a survey indicated normal radiation levels. Based on the information from the steel mill and the testing company’s RSO, no radiation exposures at the steel mill would exceed any regulatory limit. The manufacturer will perform leak testing. Corrective actions included terminating the employment of the involved employee, writing a new procedure, and providing training to technicians. Investigation will continue to determine if there may have been any radiation exposure at the recycler that exceeded limits. This event was classified as an EQP and LAS event.

Item Number 200141 - A recycling company in Ft. Worth, Texas, sent a cargo container of scrap metal to Korea, which was rejected upon arrival due to radioactivity. U.S. Customs and Border Protection seized the container when it arrived at the Terminal Island docks in San Pedro, California, on 1/19/2020. The California Health and Human Services Agency was contacted on 1/21/2020 and responded to the site the next day. Using a Fluke 451B, the initial radiation survey of the container measured 680 µR/hour at the surface, with 420 µR/hour at one foot, and 160 µR/hour at three feet (background was 10 µR/hour). The radionuclide was identified as Cs-137. DOT Exemption CA-TX-20-004 was issued and the container was returned to the recycling company on 2/18/2020. A Texas Department of State Health Services (TDSHS) inspector responded to the recycling facility on 2/19/2020. The inspector surveyed the material as it was being unloaded from the container. The source of radiation was a small steel cylinder that looked like the source from a moisture/density gauge. Pictures were sent to a gauge manufacturer who stated that the source appeared to be from one of their moisture/density gauges. TDSHS shipped the source to the manufacturer on 3/13/2020. The manufacturer confirmed that the Cs-137 source was indeed from one of their moisture/density gauges and identified the owner. The associated Am-Be source was not found. This event was classified as an EQP and LAS event.

Item Number 200253 - An environmental remediation company reported the discovery of a fixed nuclear gauge at a scrap yard on 6/15/2020. The gauge contained a Cs-137 source with an estimated activity of 222 MBq (6 mCi). The gauge shutter appeared to be stuck open or missing. Exposure rates on contact with the area where the shutter should have been were 407 mR/hour, with 23.5 mR/hour at one foot. No loose contamination was detected. No identifying information was visible on the gauge. A scrap yard representative stated that they were cleaning up a section of the yard and a load of dirt containing the gauge alarmed the radiation monitors on the way out of the facility. He said that the gauge could have been there for more than 10 years. The origin of the gauge is unknown. The remediation company packaged the gauge and took possession of it for disposal. The Ohio Department of Health performed a

survey of the scrap yard on 6/16/2020. No other radioactive material was detected. This event was classified as an EQP and LAS event.

2.2.3 Events Recently Added to NMED That Occurred Prior to FY20

Seventy-two LAS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. One of these events was considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Category 1 Source Events
None

Significant Events - Category 2 Source Events
None

Significant Events - Category 3 Source Events
Item Number 190263 - A hospital reported that a common carrier delivered a 427.6 GBq (11.56 Ci) Ir-192 high dose rate source to an incorrect location at their facility. The source was delivered to the hospital's loading dock on 6/19/2019 instead of the designated receiving location. Standard procedure is for the carrier to deliver a high dose rate source directly to the Nuclear Medicine department, where a receipt survey is performed. The source is then taken to the Radiation Oncology department, where it is stored pending source exchange. The carrier driver was behind schedule and asked one of the loading dock employees to deliver the source to the correct location. The dock employee knew that sources were previously delivered to the loading dock, so he followed the old procedure. Dock staff took the container to the Nuclear Medicine department approximately four hours after delivery. The director of Facilities Management was notified of the incident, along with Administration. Dock employees were counseled on the incident, the common carrier was notified of the improper handling of the radioactive material, and the source manufacturer was requested to send a tracking number with every shipment so that Radiation Safety staff can track the source through its shipment. The New York State Department of Health determined that the hospital's response and corrective actions were adequate.

Events of Interest
None

2.3 Medical

2.3.1 Ten-Year Data

Figure 3 displays the annual number and trend of MED events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

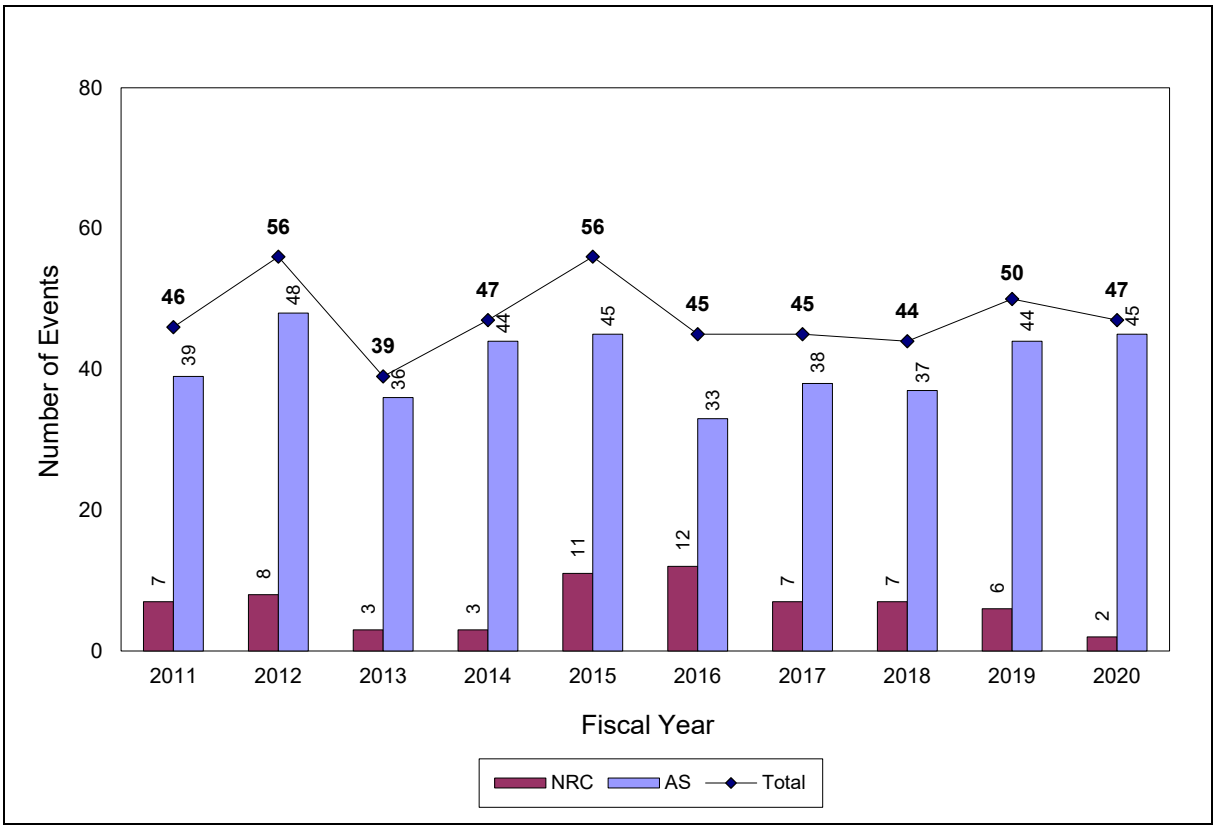

Figure 3. Medical Events (475 total)

Table 5 lists the number of MED events that were classified as Abnormal Occurrences (AOs) in NUREG-0090, *Report to Congress on Abnormal Occurrences*. Note that recent events are considered potential AOs until they complete NRC's formal AO determination process and are reported in NUREG-0090. Potential AO events are included in Table 5. Also included are events involving doses to an embryo/fetus or a nursing child (reportable per 10 CFR 35.3047). By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as an "Other" event. However, they are included here for reference.

Table 5. Medical and Embryo/Fetus or Nursing Child - AOs or Potential AOs

	Fiscal Year										
	2011	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**Total**
Medical	14	13	7	11	14	7	10	8	7	9	**100**
Embryo	1	1	2	1	1	1	0	0	0	1	**8**
Total	**15**	**14**	**9**	**12**	**15**	**8**	**10**	**8**	**7**	**10**	**108**

For this report, events classified as AOs (or potential AOs) are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.3.2 FY20 Data

Forty-seven MED events occurred in FY20, nine of which were considered significant and classified as potential AOs.

Significant Events - AOs or Potential AOs

Item Number 190558 - An eye plaque containing 13 I-125 seeds became dislodged during a procedure on 11/8/2019. Each seed contained an activity of 137.94 MBq (3.728 mCi), for a total activity of 1,793.17 MBq (48.464 mCi). The prescribed dose was 8,500 cGy (rem) with a planned treatment time of 101 hours. The eye plaque was implanted at 0745 on 11/8/2019. At approximately 0815, the patient complained of excessive pain. It was believed that the eye plaque became dislodged from its proper position. It was removed at 1731 that same day. The hospital's worst-case dose estimate to the normal sclera, conjunctiva, and cornea was 1,899 cSv (rem) at a depth of 1 mm for an 8.5-hour exposure. The dose at 2 mm for the same time period was 1,425 cSv (rem). The patient and surgeon were notified. The effects on the patient are being evaluated. The Pennsylvania Department of Environmental Protection performed a reactive inspection.

Item Number 200001 - A high dose rate applicator dislodged during a vaginal treatment on 12/13/2019. Treatment was being conducted using a remote afterloader unit with a tandem and ovoid applicator. The applicator was discovered to be dislodged at the end of the fourth of five fractions. It was unknown how long the applicator was not in the planned position or what caused it to move. The prescribed dose was 600 cGy (rad) using a 189.66 GBq (5.126 Ci) Ir-192 source. The patient was seen on 12/27/2019, 12/30/2019, and 1/6/2020 for follow-up. Observed skin effects were described as "moist desquamation" due to the applicator being dislodged from the vaginal canal and positioned against the skin. The patient is being treated with a topical cream and will be followed-up with regular skin checks. Based on the evidence observed, the medical center assumes that the applicator was against the skin long enough to deliver a skin dose in the range of 1,000 to 3,000 cGy (rad). The Pennsylvania Department of Environmental Protection performed a reactive inspection.

Item Number 200056 - During a prostate brachytherapy procedure on 1/29/2020, all 76 I-125 brachytherapy seeds were inadvertently implanted into a patient's bladder instead of the prostate. Each seed contained an activity of 12.95 MBq (350 μCi), for a total activity of 984.2 MBq (26.6 mCi). The prescribed dose to the prostate was 14,500 cGy (rad). A computed tomography (CT) scan of the patient's chest, abdomen, and pelvis was performed on 1/31/2020. There were 41 seeds identified in the bladder wall and fatty tissue surrounding the bladder. There were no seeds identified in the prostate, urethra, lungs, or other organs. The hospital assumed that patient expelled the remaining 35 seeds during urination at home. The patient, referring urologist, and oncologist were notified on 2/3/2020. The planned dose to the bladder was 7,500 cGy (rad). Preliminary calculations indicated the post-implant dose was 21,000 cGy (rad) to two cc of the bladder. However, the hospital’s one-month post-procedure estimated dose was 18,000 cGy (rad) to one cc of the bladder. The prostate base location coordinate may have inadvertently shifted and/or been misidentified prior to starting the implant procedure. Because fluoroscopy was not used to compare with the trans-rectal ultrasound image, the incorrect location would not have been identified. The hospital temporarily suspended its prostate seed implant program and performed an internal review. The cause of the event was failure to follow procedure or wrong procedure used. Corrective actions included updating the prostate implant program and performing appropriate training. The patient experienced urinary frequency, urgency, and nocturia. The patient's potential long-term effect is hemorrhagic cystitis. The South Carolina Department of Health & Environmental Control performed an investigation. This event was classified as an LAS and MED event.

Item Number 200136 - A patient received a dose to an unintended site during a gamma knife treatment for a vestibular schwannoma on 3/3/2020. The device contained Co-60 sources with a total activity of 81.33 TBq (2,198.102 Ci). At the conclusion of the treatment, it was discovered that the location of the anterior screws securing the patient's head in the treatment position had moved. Before the patient was moved from the treatment table, the patient's position was observed by the radiation oncologist, neurosurgeon, and medical physicist. The hospital performed a root cause analysis. Service engineers were called in to attempt to identify any problems. It is unknown how the screws securing the patient in the treatment position shifted from the initial position. Based on information provided by the patient and other participants associated with the event, the estimated delivery to the target coverage area was 44%, for a dose of 400 cGy (rad). An unintended dose to a region of the left temporal lobe was estimated to be 1,360 cGy (rad). On the day of the incident, the attending neurosurgeon informed the patient that the stereotactic frame had shifted during the treatment, resulting in an unknown radiation dose to the tumor. The patient was informed of the estimated dose and a plan to obtain an MRI one to two weeks after treatment and another MRI approximately three months after treatment. The hospital implemented new protocols to reduce the possibility of recurrence, including ensuring that patients understand that any movement of their head within the headframe is not anticipated and should be communicated immediately.

Item Number 200189 -A patient received a dose to two unintended locations during an intravascular brachytherapy (IVB) treatment on 4/9/2020. The IVB device contained a 40-mm source train with 16 Sr-90 sources with a total activity of 2 GBq (54.05 mCi, calibrated on 8/16/2002). The treatment site (a lesion in the right coronary artery, 30 mm in length) should have received a treatment time of 5 minutes and 57 seconds for a prescribed dose of 2,300 cGy (rad). However, the source train did not advance to the treatment site during two attempts. During the first attempt, the source train got stuck in the beta-rail catheter proximal to the treatment area for 6 minutes and 54 seconds. That area, the descending aorta, received 0.03 cGy (rad). The device was inspected and a second attempt was made. During the second attempt, the source train got stuck again in the descending aorta for 3 minutes and 41 seconds. That area received 0.02 cGy (rad). The intended treatment site received 0 cGy (rad). During each attempt, the physicians worked with the catheter to try to get the source train to move to the treatment site. The source train was able to fully retract into the IVB device each time. The hospital suspended this particular treatment program pending identification of the cause. The Texas Department of State Health Services investigated the incident. The vendor's evaluation determined that the catheter used was too small; a 7F or larger is required and a 6F was used. The source train became stuck inside the catheter due to compression and deformation of the catheter lumen. Furthermore, the vendor recommends that a failed hydraulic delivery or return be followed by manual catheter removal after 15 seconds. Corrective actions included hands-on refresher training with the vendor for all cardiologists, authorized users, and authorized medical physicists. The hospital revised their timeout protocol to address emergency procedures, adherence to the vendor's removal recommendation, and catheter requirements.

Item Number 200249 - A patient received more dose than prescribed during an I-125 eye plaque treatment. The eye plaque was implanted on 6/4/2020 with a prescribed dose of 8,500 cGy (rad). On 6/8/2020, the patient had a stroke and was admitted to a local medical center. Once the patient was able to be transported on 6/9/2020, they were moved back to hospital that performed the eye implant. Initially, the patient was not strong enough to endure the eye plaque removal procedure. The eye plaque was subsequently removed on 6/11/2020. The final dose to the tumor was 12,350 cGy (rad), which is 145.3% of the prescribed dose. The Arizona Department of Health Services investigated the event.

Item Number 200275 - A patient received a dose to an unintended site during a high dose rate afterloader treatment for ovarian cancer on 7/8/2020. The prescribed dose to the intended organ was 2,400 cGy (rad). Due to an incorrect catheter length entry in the treatment delivery system, an unintended dose of 2,180 cGy (rad) was estimated to have been delivered to the large bowel. The dose delivered to the intended

organ was estimated to be 0 cGy (rad). The patient and her physician were notified. The university is investigating the incident and it will be reviewed by the California Health and Human Services Agency.

Item Number 200320 - A patient received a dose to an unintended site during a Y-90 microsphere treatment. The patient was prescribed an ablative dose of 22,500 cGy (rad) to the right lobe of the liver. The patient was administered 2.66 GBq (62.9 mCi) of Y-90 on 8/5/2020. Post implant Bremsstrahlung imaging indicated that 2.01 GBq (54.39 mCi) was unintentionally delivered to segment 4 of the left lobe of the liver, for a dose of 16,000 cGy (rad). The patient and referring physician were notified. This event was likely caused by incorrect placement of the tip of the intra-arterial catheter into a branch of the left hepatic artery. A contributing factor was the patient's extremely distorted anatomy, due to atrophy of the right lobe of the liver and hypertrophy of the left lobe. The patient was asymptomatic and liver tests for five days after the treatment were stable. However, radiation damage to the liver may not become apparent for up to two weeks post treatment. To prevent recurrence, additional imaging will be acquired when clinically indicated.

Item Number 200363 - An incorrect dose was delivered to a patient during a Y-90 microsphere treatment on 8/27/2020. The hospital performed a split-dose procedure on the patient's anterior right liver lobe (segments 5 and 8) and posterior right liver lobe (segments 6 and 7). Each site was prescribed a dose of approximately 12,400 cGy (rad) using 2.22 GBq (60 mCi) of Y-90 microspheres. The remaining normal liver tissue was to receive a background dose of less than 5,000 cGy (rad). The posterior site was treated first and then the catheter was moved to the anterior position. Post treatment survey results of the acrylic beta shield waste containers indicated that 99% of the 4.44 GBq (120 mCi) activity was delivered to the patient. Routine post therapy Bremsstrahlung imaging demonstrated that the posterior site received 0.74 GBq (20 mCi) and 3,500 cGy (rad), while the anterior site received 3.7 GBq (100 mCi) and between 17,000 and 18,000 cGy (rad). The normal liver tissue received between approximately 8,000 and 8,500 cGy (rad). There was no evidence of extrahepatic activity on the routine post therapy Bremsstrahlung imaging. The hospital concluded that there was no definitive cause for the event. A guide sheath was used to position the trans-femoral catheter to each target area and the position was confirmed using fluoroscopy. The positioning of the catheter was documented on immediate pre-therapy time stamped images to be acceptable and in appropriate position prior to administration. The physician believed that the catheter slipped after initial placement, resulting in the medical event. The hospital will no longer conduct split dose procedures. The Ohio Department of Health conducted a reactive inspection on 9/16/2020. They confirmed that the hospital followed required regulations, guidance, and policies/procedures.

<u>Events of Interest</u>

Item Number 190569 - A patient treated with Lu-177 dotatate on 11/14/2019 inadvertently received a skin injury. It was determined during her infusion that the Foley catheter was leaking. After the leak was identified, proper decontamination procedures were performed. The patient was instructed upon discharge that there was a chance for skin injury. The estimated skin dose was 700 cGy (rad). On 11/18/2019, the patient informed her provider that there was skin irritation in the peri-gluteal and peri-labia areas. It was determined that this was skin injury consistent with radiation injury.

Item Number 200062 - A patient's kidneys received more dose than intended during a Lu-177 dotatate treatment for pancreatic cancer on 2/4/2020. The patient was prescribed an activity of 7.4 GBq (200 mCi) and received 7.47 GBq (202 mCi). During a typical treatment, an amino acid infusion begins 30 minutes prior to the radioactive drug administration, to protect the kidneys from drug toxicity and lower the kidneys' radiation dose. However, during this event, the treatment team forgot to start the amino acid infusion. Approximately 20 minutes after the administration began, the technologist discovered that the amino acid infusion had not been started, at which point it was started. As a result of the error, the kidneys received an estimated dose of 740 cSv (rem), instead of the intended dose of 490 cSv (rem). The patient, RSO, and staff were notified. The Minnesota Department of Health investigated the incident. The amino acid infusion had not been started because the intravenous (IV) line connected to the fluid bag

containing the amino acid solution remained clamped. Normally, a clamped line will result in an alarm. However, because the fluid bag containing the amino acid solution was placed on a secondary line, the primary line was still able to flow saline. The nurse did not notice that the IV chamber was not dripping and was unaware that the amino acid line was still clamped. When the nuclear medicine technologist arrived to administer the Lu-177 dotatate, they did not notice that the amino acid infusion had not started and began the administration. Commencement of the amino acid infusion was listed on the checklist that was available for the technologist, but the checklist was not consulted. While there were no expected long-term effects from the error, the patient's renal function will be tested over the next 36 months. Corrective actions include switching the fluid bag containing the amino acid solution to a separate primary IV line, which will result in an alarm when the line is clamped. That change was communicated to the nursing staff, along with a reminder of the importance of ensuring the amino acid infusion has begun. The nuclear medicine technologist will take a formal, documented pause with nursing staff prior to the administration of Lu-177 dotatate to ensure that the amino acid infusion has begun.

Item Number 200083 - A patient received a dose to an unintended site during skin therapy on 2/24/2020. The patient was scheduled to receive five fractions, at 750 cGy (rad) per fraction, on five different skin lesions of the left hand. The incident involved a high dose rate afterloader unit and a 288.97 GBq (7.81 Ci) Ir-192 source. After the first fraction was delivered, physicists reviewing the case noted that the 15 catheters were digitized in reverse order and determined that the patient was under dosed by 56.25% overall. Lesion one received no dose, lesion two received 50% of the planned dose, lesion three received 95.5% of the planned dose, lesion four received 100% of the planned dose, and lesion five received no dose. In addition, non-target skin (normal skin) unintended to be irradiated received 750 cGy (rad). The patient’s treatment had been simulated on 2/17/2010, at which time a Freiberg applicator was sewn into a custom-made immobilization device that was fashioned about the patient's left hand. The catheters were numbered 1 through 15, beginning with number one at the thumb and ending with number 15 at the pinky finger. On the following day, a physicist planned the case after discussing the Freiberg applicator orientation with a therapist, who was not present at the simulation. The physicist digitized the catheters in the treatment planning system starting with the pinky finger as number one and ending with the thumb at number 15. Following physician approval of an optimal plan, the second physicist performed an independent chart check, and in doing so noted that the 3D image appeared to depict the catheter orientation properly. Corrective actions were taken to improve the simulation, independent physics check, and time-out prior to delivering the first treatment. Informative set-up pictures will be taken, clearly labeling orientation of any devices. Catheters will be numbered in a clockwise fashion for consistency. A "bb pellet" will be placed in catheter one as a redundant numbering safety feature. The physicist planning a brachytherapy case will be present during the simulation. The independent check must include reconciling the 3D plan printout with all set-up pictures and should be performed by a physicist who was not involved in the case. The 3D printout must be compared to the applicator once applied to the patient.

Item Number 200135 - A patient received a dose to an unintended location during the first fraction of a vaginal cylinder treatment using a high dose rate afterloader on 3/20/2020. The afterloader contained a 271.95 GBq (7.35 Ci) Ir-192 source. Hospital staff had difficulty removing the cylinder post-treatment. They determined that the cylinder had perforated the patient's vaginal wall at some time following pre-treatment imaging and prior to completion of the treatment. They determined that the cylinder moved 3.5 cm from its original position and protruded into the bowel space. The Wisconsin Department of Health Services performed an investigation on 3/25/2020. The patient was prescribed 600 cGy (rad) to the surface of the vaginal cylinder. Using CT imaging, the hospital confirmed the proper placement of the cylinder prior to treatment. Staff performed all pre-treatment checks, connected the patient to the afterloader unit, and initiated treatment. Everything appeared to be as expected. However, it was very difficult for the authorized user to remove the cylinder following treatment. The hospital believed that the bowel conformed to the shape of the cylinder during part or all of treatment, causing a much larger volume of the bowel to receive an elevated radiation dose as compared to the treatment plan. The hospital calculated a worst-case, unintended dose of 600 cGy (rad) to the bowel. The patient and referring

physician were notified. The authorized user did not expect the patient to experience any radiological consequences to the bowel. The patient required immediate surgery to suture the vaginal wall. The rest of the patient's fractions were cancelled. The hospital identified two corrective actions. At the time of cylinder insertion, they will put a pen mark on the inside of the patient's leg to mark the external terminus of the cylinder. Then during the final pre-treatment check, they can positively confirm that the cylinder is in the correct position. That will improve the previous final pre-treatment check, which simply verified that the cylinder had not come out. The previous treatment convention allowed physicians to prescribe the treatment dose to either the surface of the cylinder or 0.5 cm beyond the surface. Future treatments will only prescribe dose to the surface of the cylinder.

Item Number 200208 - A patient received a dose to an unintended location during the third and final fraction of a vaginal cylinder treatment using a high dose rate afterloader on 4/22/2020. The afterloader contained a 407 GBq (11 Ci) Ir-192 source. There were no problems with the first two fractions. During the third fraction, the vaginal cylinder was inserted through the body wall weakened by a previous surgery (robotic hysterectomy). The penetration allowed the source to move about 4 cm past the treatment area. As a result, the treatment area only received 25% of the volume coverage instead of the planned 95% volume coverage. The patient was notified.

Item Number 200228 - A patient received more dose than prescribed during the first fraction a vaginal cylinder treatment using a high dose rate afterloader on 5/12/2020. The afterloader used a 355.28 GBq (9.60221 Ci) Ir-192 source. The written directive initially prescribed 700 cGy (rad) for three fractions to a depth of 5 mm. Due to the relatively small diameter of the cylinder (20 mm), the radiation oncologist decided to change the written directive to 700 cGy (rad) for three fractions to the surface of the cylinder. The treatment plan was created, the doses to the normal tissue (bladder, rectum, and bowel) were accepted by the radiation oncologist, and the treatment plan was approved. The treatment was then delivered to the patient. However, on 5/14/2020, it was discovered that the prescription isodose line did not appear to fall on the surface of the cylinder. On 5/15/2020, it was discovered that the 700 cGy (rad) isodose line was at about 4.2 mm from the surface of the cylinder and the dose to the points on the surface of the cylinder were found to be 158.3% of the prescription, or 1,108.1 cGy (rad), on average. In the opinion of the radiation oncologist, the dose delivered did not negatively affect the patient and the doses to the normal tissue were acceptable dose levels for this type of treatment. Additionally, had the plan been normalized to the surface of the cylinder, the radiation oncologist would more than likely have increased the dose. The cause of the event was human error. Calculated dose to the points placed on the surface of the cylinder were not carefully checked prior to approving, exporting, and delivering the treatment plan. The treatment planning system and an independent dose-validation software both reflected doses above the 700 cGy (rad) per fraction specified in the written directive, but the difference was not noticed by the treatment planner. Corrective actions included creation of check sheets for all treatments with the afterloader, an independent review by a physics/dosimetry team not involved in the patient's treatment, better communication, treatment planning system and independent dose validation comparisons against the written directive, and staff training.

Item Number 200258 - A patient received a dose to an unintended location during the first fraction of a vaginal cylinder treatment using a high dose rate afterloader on 6/23/2020. The afterloader contained a 278.277 GBq (7.521 Ci) Ir-192 source. The patient's treatment plan called for three fractions of 700 cGy (rad) delivered to the vagina. After the first fraction was administered, the authorized user and radiation therapist noted the presence of fecal matter on the applicator. A review of the CT images determined that the applicator was most likely placed in the patient's rectum instead of the vagina. Had the procedure been performed correctly, the expected dose to the rectum was 450 cGy (rad). Approximately 1% of the rectum received a dose of 1,250 cGy (rad) and approximately 50% of the rectal volume received a dose of 163 cGy (rad). Ninety percent of the target volume received 520 cGy (rad), or 73.78% of the prescribed dose. The acute effect of the dose to the rectum was expected to include temporary acute mucosal denudation, which should resolve in 21 days. That process may result in increased stool frequency and urgency. The

patient was notified. The patient subsequently cancelled all future appointments. The cause of the event was determined to be inadequate supervision by the authorized user. Corrective actions included generating a new written procedure.

Item Number 200378 - A patient received a dose to an unintended location during the first fraction of a vaginal cylinder treatment using a high dose rate afterloader on 9/1/2020. A patient was previously prescribed to receive a total treatment of 6,060 cGy (rad) to the vaginal cuff, but only received 4,860 cGy (rad) using external sources. The patient was to receive two boost treatments to the vaginal cuff of 600 cGy (rad) each using an afterloader with a 255.781 GBq (6.913 Ci) Ir-192 source. On 9/14/2020, while setting up for the second boost treatment, the hospital identified that the source catheter tube used in the first boost treatment was too long; it measured 120 cm instead of the intended 113 cm. Therefore, the first boost treatment was delivered to the surface of the lower vagina instead of the vaginal cuff. The lower vagina received 600 cGy (rad). The patient and physician were notified. The plan was revised to perform a third boost treatment to the area that was underexposed in the first treatment. The cause of the event was human error. Corrective actions included labeling the catheters with lengths, modifying procedures, and providing additional instruction to personnel. The hospital did not expect any adverse effects to the patient.

Item Number 200393 - A patient received a dose to an unintended location during the third fraction of a vaginal cylinder treatment using a high dose rate afterloader on 9/22/2020. The afterloader contained a 277.463 GBq (7.499 Ci) Ir-192 source. The patient was prescribed a 3,000 cGy (rad) therapeutic dose to the vaginal cuff to be delivered over a series of five fractionated treatments of 600 cGy (rad) each. It is unclear if an authorized medical physicist was physically present at the time of administration. Rather than inserting the applicator into the vagina, the applicator was inserted into the rectal cavity. The error was not discovered until after the treatment was delivered. The dose delivered to the vaginal cuff was 146 cGy (rad), which was 76% less than prescribed. The rectum was intended/expected to receive 153 cGy (rad) but received 394 cGy (rad) to 50% of the rectum volume, which was 157% over intended. The hospital's procedures lacked the specificity necessary to ensure the administration was in accordance with the written directive. Acceptance testing on the treatment planning system, in particular the accuracy of the software used to determine sealed source position from radiographic imaging, was reviewed by inspectors. The CT images accurately reflected the source position and incorporated that position into isodose plots. Inspectors concluded that the root cause was failure to properly place the applicator and failure of the treatment team to properly identify the error in subsequent radiographic images. The hospital modified their written procedures to prevent recurrence. The patient and referring physician were notified. No adverse medical impact to the patient was reported.

Embryo/Fetus or Nursing Child Dose Events - AOs or Potential AOs

Doses to an embryo/fetus or nursing child are reportable per 10 CFR 35.3047. By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as "Other" events. However, it is appropriate to also discuss these events in this section. One of these events occurred in FY20.

Item Number 200051 - An embryo/fetus received a radiation dose when a patient who was unknowingly pregnant received an Lu-177 dotatate therapy treatment on 1/9/2020. A serum pregnancy test administered to the patient on 1/3/2020 was negative. On 1/9/2020, prior to the therapy treatment, the patient reported that there was no chance of being pregnant. The patient was then administered 7.53 GBq (203.5 mCi) of Lu-177 dotatate. This was the second of four treatments, with the first treatment occurring on 11/13/2019. On 1/28/2020, the patient notified her medical oncologist that she was pregnant. The medical oncologist informed the treating physician the same day. On 1/29/2020, the treating physician contacted the patient and learned that the possible date of conception was 1/3, 1/4, or 1/5/2020. The dose to the embryo/fetus was calculated to be 14.3 cSv (rem). The treating physician reviewed the radiation effects with the patient on 1/31/2020, stating that there was no expected increased risk of fetal death or anatomical malformations at delivery. The patient terminated the pregnancy on 2/18/2020 and scheduled

her next treatment. To prevent recurrence, the hospital revised their policy to require a negative serum pregnancy test within 48 hours prior to treatment. The NRC performed a special inspection on 2/5/2020 to review the event. A medical consultant concurred with the hospital's evaluation of the event, including the dose calculation.

2.3.3 Events Recently Added to NMED That Occurred Prior to FY20

Four MED events and no embryo/fetal dose events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of the MED events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - AOs or Potential AOs
None

Events of Interest
None

Embryo/Fetus or Nursing Child Dose Events - AOs or Potential AOs
None

2.4 Radiation Overexposure

2.4.1 Ten-Year Data

Figure 4 displays the annual number and trend of EXP events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

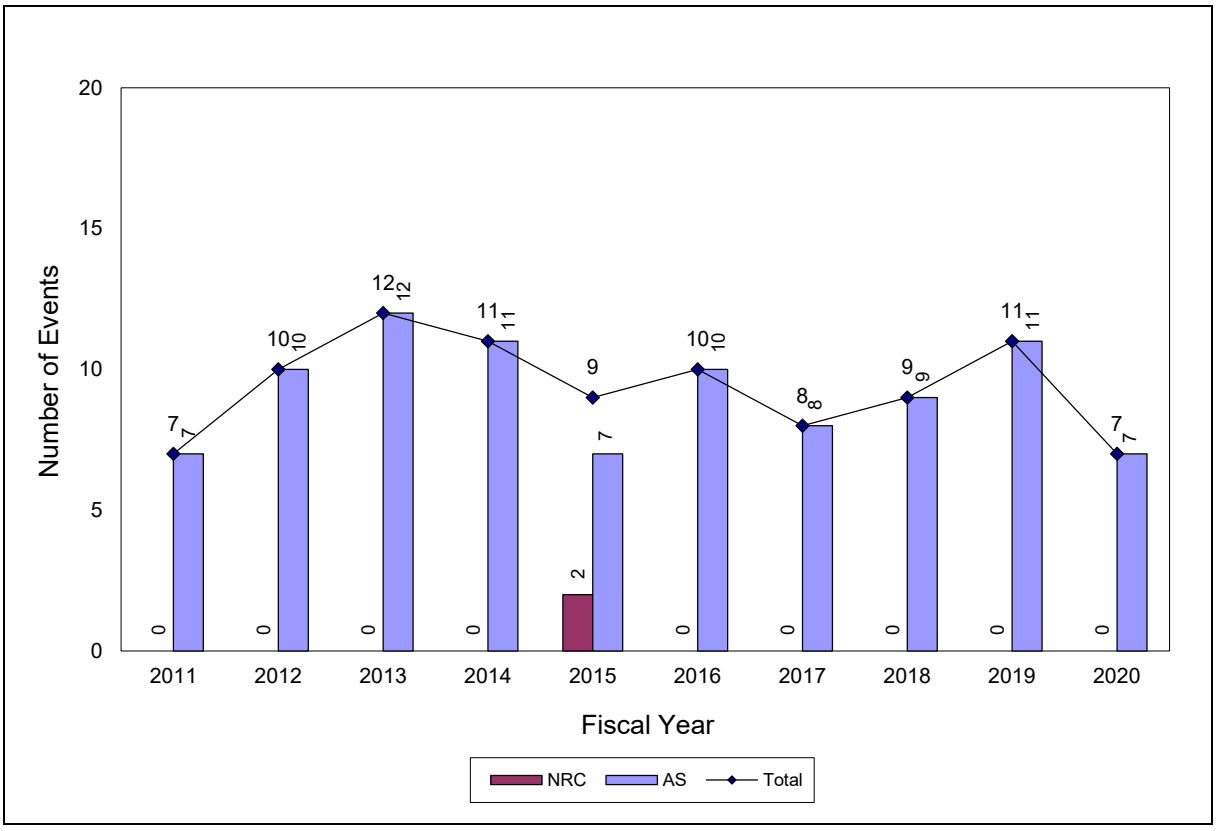

Figure 4. Radiation Overexposure Events (94 total)

The significance of individual EXP events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, events requiring immediate or 24-hour reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 6 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If an event involved exposures that were reportable in more than one category, the event is counted in only the most restrictive category.

Table 6. EXP Events Classified by CFR Reporting Requirement

	Fiscal Year										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total
Immediate	1	1	0	0	0	1	0	1	1	2	**7**
24-Hour	0	4	1	3	4	1	2	3	4	0	**22**
30-Day	6	5	11	8	5	8	6	5	6	5	**65**
Total	**7**	**10**	**12**	**11**	**9**	**10**	**8**	**9**	**11**	**7**	**94**

2.4.2 FY20 Data

Seven EXP events occurred in FY20, two of which were considered significant.

Significant Events - Immediate Reporting

Item Number 200221 - A radiation overexposure event occurred at a plastics manufacturing company after a 3.52 GBq (95 mCi) Cs-137 source separated from a broken fixed gauge. The gauge had only been installed for about six months. The locking mechanism broke off the gauge housing on 5/10/2020. The shutter could still be locked in the closed position but could no longer be held in the open position. The company used a zip-tie to hold the shutter open in order to continue facility operations. The gauge did not present a radiation exposure risk to any individual. A replacement gauge was expected about 7/9/2020. The gauge experienced a second failure on 6/23/2020. The gauge could still be closed but could not be locked in the closed position. A series of zip-ties was installed to hold the rotary element in the open position. The gauge experienced a third failure on 6/30/2020. The rotary element, with the Cs-137 source attached to it, came partially out of the gauge. When employees tried to put the element back in, it came apart in pieces. The employees did not realize that one of the pieces was the source. An employee picked up the source and gave it to another employee, who put it in his shirt pocket. After becoming aware of the event, the RSO contacted a licensed service company, who put the source in a lead pig and secured it at the facility. The company also consulted with the Radiation Emergency Assistance Center/Training Site (REAC/TS). One individual (radiation worker) received a whole body DDE exposure of between 38 and 41 cSv (rem) (partial body, not uniform, highest exposure to the torso/chest), a skin exposure SDE to the chest of between 87 and 249 cGy (rad), and an extremity SDE exposure to one hand of 31 cGy (rad). A second individual (radiation worker) received a whole body DDE exposure of between 0.26 and 0.33 mSv (26 and 33 mrem), with 1 cGy (rad) to one hand and 24 cGy (rad) to the other hand. A third individual (non-radiation worker/member of the public) received a whole body DDE exposure of 0.03 mSv (3 mrem), whole body SDE skin exposure of 0.27 mSv (27 mrem), with 2 cGy (rad) DDE to one hand and 30 cGy (rad) SDE to the other hand. Four other individuals (one radiation worker and three non-radiation workers/members of the public) received small exposures of less than 0.1 mSv (10 mrem) whole body DDE and less than 0.08 mSv (8 mrem) whole body SDE skin. The gauge was shipped to the manufacturer's facility in Indiana for evaluation. During shipment, the package failed and the broken pieces of the gauge were lost; only the gauge housing arrived in Indiana. The manufacturer could not identify the specific cause of the failure other than an external force of some kind. NRC participated in an onsite inspection in Indiana. The plastics company has 16 more of these gauges which they will inspect. As of 9/18/2020, this incident had a final International Nuclear Event Scale rating level of 2. This event was classified as an EQP and EXP event, as well as a potential Abnormal Occurrence.

Item Number 200312 - A radiography crew was overexposed during operations at an asphalt plant in Mulga, Alabama, on 8/3/2020. While the radiography source was being exposed, a magnetic stand fell from the side of a tank and crushed part of the guide tube. Several attempts by the crew to retract the source into the exposure device using the crank were unsuccessful. Additional shielding was used to reduce radiation exposure. Re-rounding the guide tube with pliers and a hammer was unsuccessful. The

crew successfully retracted the source after cutting the guide tube to free up enough space to pull the source through the crimped portion. Before performing the source retrieval, the three individuals involved moved their dosimetry to their wrists to account for accurate doses to their extremities. Their dosimetry badges were sent for emergency processing. The radiography exposure device was sent to the manufacturer for investigation. The radiation doses to the three individuals were: 63.577 cSv (rem) DDE and 64.486 cSv (rem) SDE to one individual, 10.439 cSv (rem) DDE and 10.402 cSv (rem) SDE to the second individual, and 2.608 cSv (rem) DDE and 2.637 cSv (rem) SDE to the third individual. The two individuals with doses in excess of 5 cSv (rem) DDE were removed from radiography operations. Corrective actions included procedure modifications and personnel training. Changes included ensuring that the magnetic stand is rated for the weight placed on it, the stand surface is free of debris and rust, applying stress to the stand to determine the breaking point, and using the right tool for the application. The Alabama Department of Public Health performed an investigation. As of 12/21/2020, this incident had a final International Nuclear Event Scale rating level of 2. This event was classified as an EQP and EXP event, as well as a potential Abnormal Occurrence.

Significant Events - Within 24-Hour Reporting
None

Events of Interest
Item Number 200158 - A radiation overexposure event occurred at a petroleum facility on 2/13/2020. Two contractor employees (members of the public) removed and reinstalled a fixed gauge that contained an 18.5 GBq (500 mCi) Cs-137 source. Because the work was unplanned and unmonitored, the gauge was not properly shuttered or locked out. Exposure estimates indicated that one worker received a total exposure of 7.385 mSv (738.5 mrem). A majority of that exposure was received during reinstallation of the source holder, when the radiation beam was pointed at the worker for 15 minutes. The other worker received less than 0.01 mSv (1 mrem). The cause was human error. Corrective actions included modifying procedures, contractor training, and the work permitting process.

2.4.3 Events Recently Added to NMED That Occurred Prior to FY20

One EXP event was recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. This event was not considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate Reporting
None

Significant Events - Within 24-Hour Reporting
None

Events of Interest
None

2.5 Release of Licensed Material or Contamination

2.5.1 Ten-Year Data

Figure 5 displays the annual number and trend of RLM events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

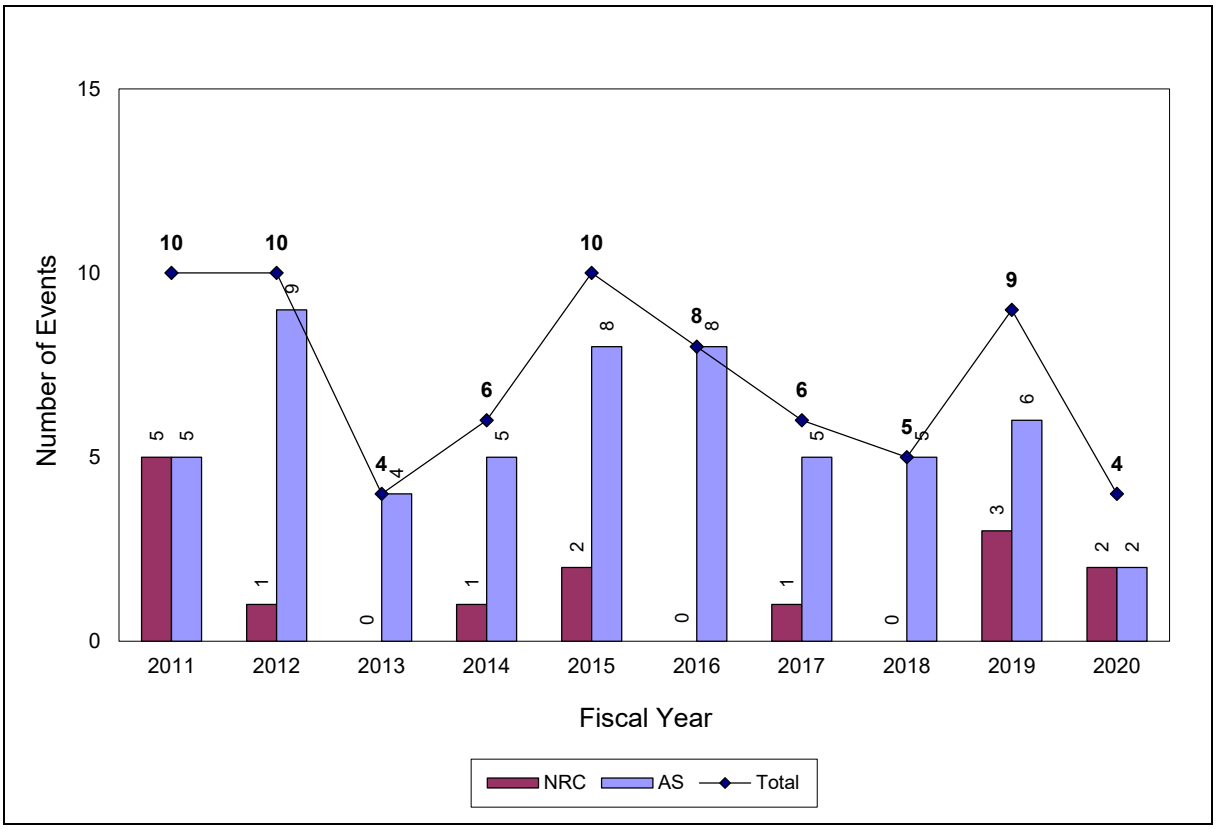

Figure 5. Release of Licensed Material or Contamination Events (72 total)

The significance of individual RLM events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, events requiring immediate reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 7 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If an event involved exposures that were reportable in more than one category, the event is counted in only the most restrictive category.

Table 7. RLM Events Classified by CFR Reporting Requirement

	Fiscal Year										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total
Immediate	0	2	1	1	1	1	3	1	1	1	**12**
24-Hour	9	6	2	3	9	7	3	4	6	3	**52**
30-Day	1	2	1	2	0	0	0	0	2	0	**8**
Total	**10**	**10**	**4**	**6**	**10**	**8**	**6**	**5**	**9**	**4**	**72**

2.5.2 FY20 Data

Four RLM events occurred in FY20, one of which was considered significant.

Significant Events - Immediate Reporting

Item Number 190510 - A hospital's hot laboratory and adjacent areas were radioactively contaminated when an authorized user (AU) intentionally broke two I-131 capsules containing a total activity of 1.11 GBq (30 mCi) on 10/15/2019. He did this after a patient with hyperthyroidism stated that they could not swallow the capsules. The AU proceeded to break the capsules open in order to pour the contents into water to more easily administer the dose to the patient. The patient and AU were in the treatment room when the AU began to break the capsules. The AU then went to the hot laboratory, where he successfully broke the capsules using a syringe needle. A nuclear technician inquired as to what was happening, realized that there may be a contamination issue, and contacted the RSO. A survey identified contaminated areas/items including the hot laboratory, hallway in front of the hot laboratory, counter of the treatment room, scrub pants, shoes, and socks. The RSO placed the scrub pants, shoes, and socks an area for decay-in-storage. He proceeded to clean the areas that were least contaminated (hallway and treatment room) but could not get them completely clean. The hot laboratory and treatment room were sealed off and secured. The hallway was posted and cordoned off. The staff who were working in the area (RSO, assistant RSO, nuclear technician, and AU) were monitored for thyroid uptake; results were negative. The patient was not monitored for thyroid uptake (the patient had an I-123 treatment one week prior to this incident). The patient was not administered the I-131. The Georgia Department of Natural Resources performed a reactive inspection on 10/30/2019. They verified that the contaminated areas had physical barriers to prevent inadvertent entry and signs posted to warn individuals. The RSO stated that the laboratory will not re-open until contamination levels reach background, approximately 80 days from the time of the incident. The RSO removed the involved AU's right to administer any therapeutic doses. Training will be provided to AUs, technologists, and residents who are involved in administering radioactive material. A technologist will be required to be present in the room when I-131 is administered. Instructions will be added to hospital procedures about not opening or breaking capsules containing radioactive material.

Events of Interest

None

2.5.3 Events Recently Added to NMED That Occurred Prior to FY20

Two RLM events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. These events were not considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate Reporting

None

Events of Interest
None

2.6 Leaking Sealed Sources

2.6.1 Ten-Year Data

Figure 6 displays the annual number and trend of LKS events that occurred during the 10-year period. The trend analysis determined that the data do not represent statistically significant trends (indicated by the absence of trend lines).

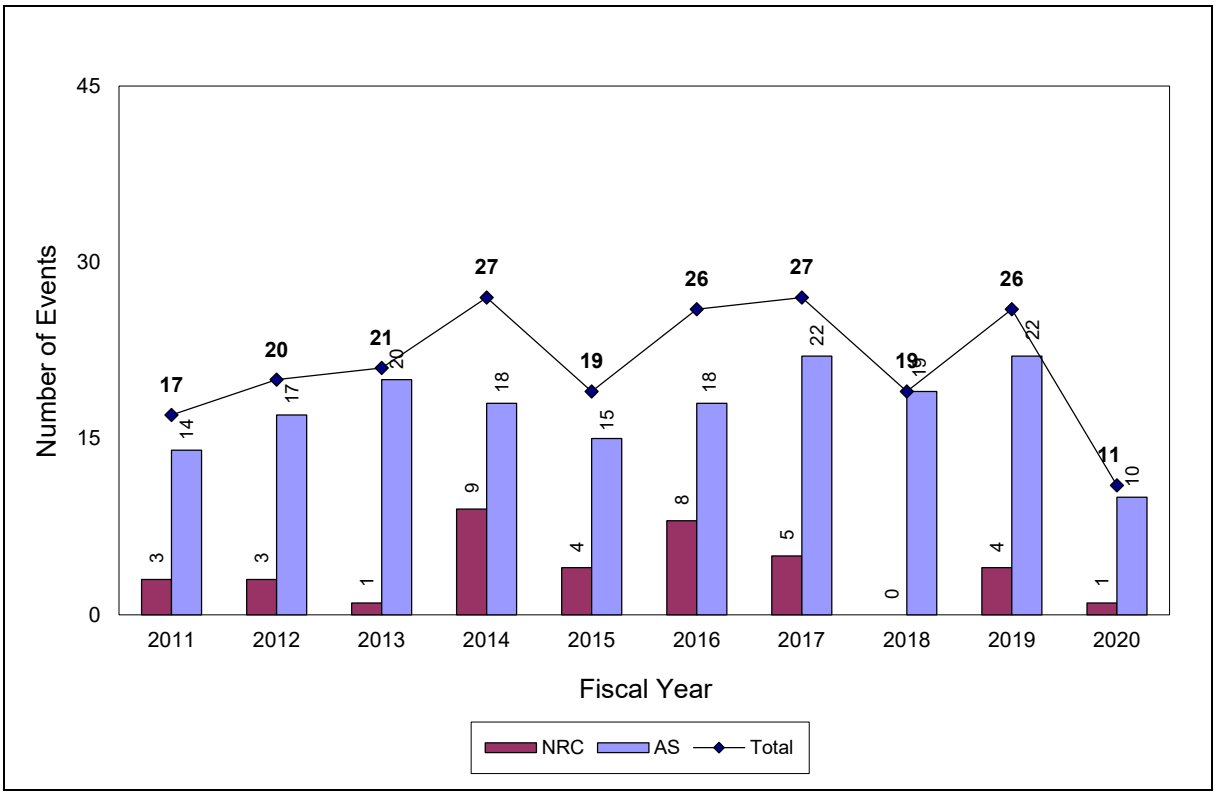

Figure 6. Leaking Sealed Source Events (213 total)

It is not possible to discern the significance of LKS events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). There are essentially no immediate or 24-hour reporting requirements for leaking sources. The exception is 10 CFR 39.77(a), which is an immediate report to the NRC Regional office of a ruptured well logging source. Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.6.2 FY20 Data

Eleven LKS events occurred in FY20, none of which were considered significant.

Significant Events
None

Events of Interest
None

2.6.3 Events Recently Added to NMED That Occurred Prior to FY20

Three LKS event was recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added

and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events
None

Events of Interest
None

2.7 Equipment

2.7.1 Ten-Year Data

Figure 7 displays the annual number and trend of EQP events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

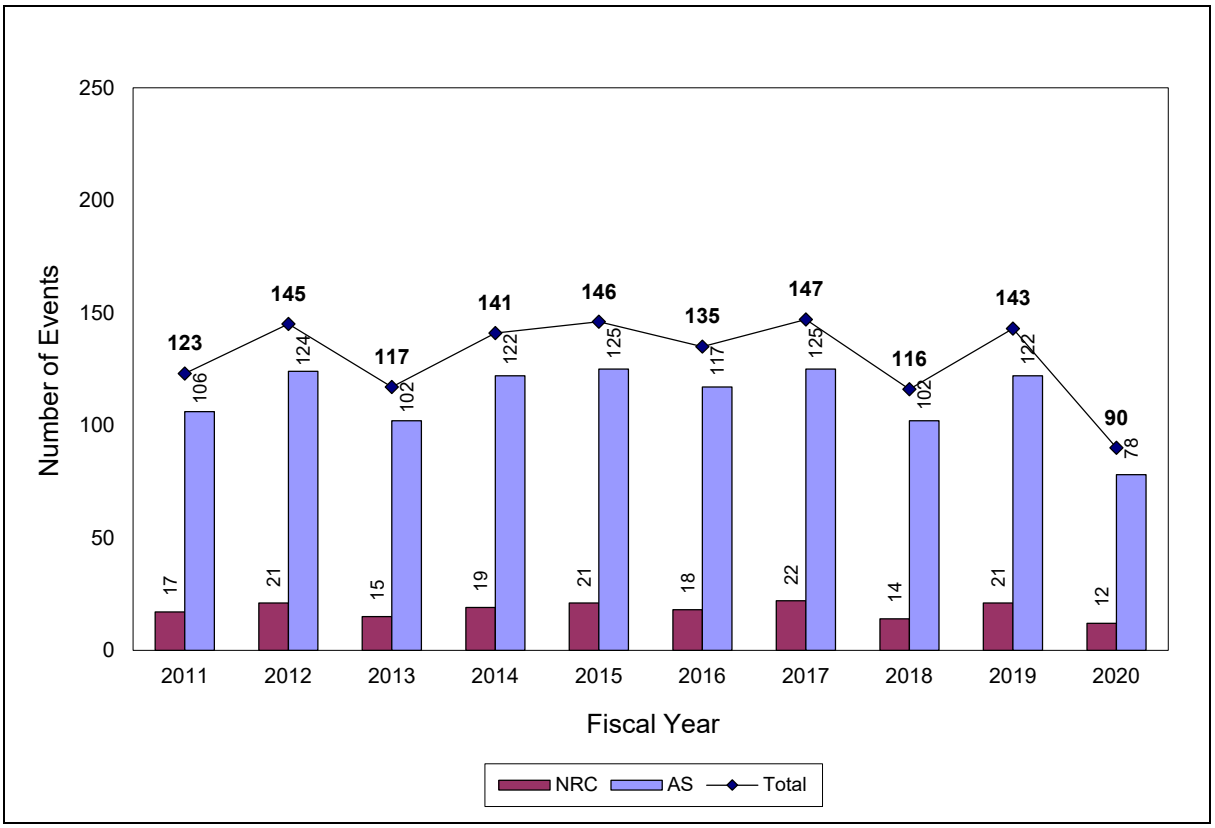

Figure 7. Equipment Events (1,303 total)

It is not possible to discern the significance of EQP events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5) because essentially all of the CFRs associated with EQP events require reporting within 24-hours. Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.7.2 FY20 Data

Ninety EQP events occurred in FY20, three of which were considered significant.

Significant Events

Item Number 200221 - A radiation overexposure event occurred at a plastics manufacturing company after a 3.52 GBq (95 mCi) Cs-137 source separated from a broken fixed gauge. The gauge had only been installed for about six months. The locking mechanism broke off the gauge housing on 5/10/2020. The shutter could still be locked in the closed position but could no longer be held in the open position. The company used a zip-tie to hold the shutter open in order to continue facility operations. The gauge did not present a radiation exposure risk to any individual. A replacement gauge was expected about 7/9/2020. The gauge experienced a second failure on 6/23/2020. The gauge could still be closed but could not be locked in the closed position. A series of zip-ties was installed to hold the rotary element in the open

position. The gauge experienced a third failure on 6/30/2020. The rotary element, with the Cs-137 source attached to it, came partially out of the gauge. When employees tried to put the element back in, it came apart in pieces. The employees did not realize that one of the pieces was the source. An employee picked up the source and gave it to another employee, who put it in his shirt pocket. After becoming aware of the event, the RSO contacted a licensed service company, who put the source in a lead pig and secured it at the facility. The company also consulted with the Radiation Emergency Assistance Center/Training Site (REAC/TS). One individual (radiation worker) received a whole body DDE exposure of between 38 and 41 cSv (rem) (partial body, not uniform, highest exposure to the torso/chest), a skin exposure SDE to the chest of between 87 and 249 cGy (rad), and an extremity SDE exposure to one hand of 31 cGy (rad). A second individual (radiation worker) received a whole body DDE exposure of between 0.26 and 0.33 mSv (26 and 33 mrem), with 1 cGy (rad) to one hand and 24 cGy (rad) to the other hand. A third individual (non-radiation worker/member of the public) received a whole body DDE exposure of 0.03 mSv (3 mrem), whole body SDE skin exposure of 0.27 mSv (27 mrem), with 2 cGy (rad) DDE to one hand and 30 cGy (rad) SDE to the other hand. Four other individuals (one radiation worker and three non-radiation workers/members of the public) received small exposures of less than 0.1 mSv (10 mrem) whole body DDE and less than 0.08 mSv (8 mrem) whole body SDE skin. The gauge was shipped to the manufacturer's facility in Indiana for evaluation. During shipment, the package failed and the broken pieces of the gauge were lost; only the gauge housing arrived in Indiana. The manufacturer could not identify the specific cause of the failure other than an external force of some kind. NRC participated in an onsite inspection in Indiana. The plastics company has 16 more of these gauges which they will inspect. As of 9/18/2020, this incident had a final International Nuclear Event Scale rating level of 2. This event was classified as an EQP and EXP event, as well as a potential Abnormal Occurrence.

Item Number 200225 - A radiopharmaceutical manufacturing company reported that an explosive chemical reaction occurred inside a production hot cell on 5/13/2020. The explosion occurred during a rubidium dissolution process that involved more than 37 GBq (1 Ci) of Sr-82. The explosion damaged the latch on the hot cell's back door, forcing the door open approximately six inches. The employees performing the dissolution process immediately activated the hot cell fire suppression system to extinguish the fire, closed the hot cell door, and placed the production area in a secure state. The open hot cell door released airborne radioactive material to a localized area inside the controlled and posted production area. Six employees in the vicinity of the hot cell were contaminated with Sr-82. Contamination was also found on equipment and the floor immediately around the hot cell. Analysis of air samples taken in the affected area indicated the presence of Sr-82, Sr-85, Rb-83, Rb-84, and Rb-86. Radiological surveys confirmed that there was no detectable release of radioactive material to uncontrolled areas adjacent to the hot cell production area. The employees and affected area were decontaminated. Estimates of the potential dose to the six employees and the total activity released from the hot cell were developed. The majority of the radioactive material remained in the process vessel inside the hot cell. Personnel exposure analysis, including bioassays, indicated exposures of less than 0.1 mSv (10 mrem) from inhalation and less than 0.5 mSv (50 mrem) to the skin. Expedited processing of dosimetry indicated a maximum exposure of 1.42 mSv (142 mrem). The area was released for normal operations within the same business day. The company performed a formal root cause analysis on 5/14/2020. Corrective actions included repair/replacement of damaged equipment, procedural changes, and personnel training.

Item Number 200312 - A radiography crew was overexposed while working at an asphalt plant in Mulga, Alabama, on 8/3/2020. While the radiography source was being exposed, a magnetic stand fell from the side of a tank and crushed part of the guide tube. Several attempts by the crew to retract the source into the exposure device using the crank were unsuccessful. Additional shielding was used to reduce radiation exposure. Re-rounding the guide tube with pliers and a hammer was unsuccessful. The crew successfully retracted the source after cutting the guide tube to free up enough space to pull the source through the crimped portion. Before performing the source retrieval, the three individuals involved moved their dosimetry to their wrists to account for accurate doses to their extremities. Their dosimetry badges were

sent for emergency processing. The radiography exposure device was sent to the manufacturer for investigation. The radiation doses to the three individuals were: 63.577 cSv (rem) DDE and 64.486 cSv (rem) SDE to one individual, 10.439 cSv (rem) DDE and 10.402 cSv (rem) SDE to the second individual, and 2.608 cSv (rem) DDE and 2.637 cSv (rem) SDE to the third individual. The two individuals with doses in excess of 5 cSv (rem) DDE were removed from radiography operations. Corrective actions included procedure modifications and personnel training. Changes included ensuring that the magnetic stand is rated for the weight placed on it, the stand surface is free of debris and rust, applying stress to the stand to determine the breaking point, and using the right tool for the application. The Alabama Department of Public Health performed an investigation. As of 12/21/2020, this incident had a final International Nuclear Event Scale rating level of 2. This event was classified as an EQP and EXP event, as well as a potential Abnormal Occurrence.

Events of Interest

Item Number 200078 - A construction materials testing company reported the theft and recovery of a moisture/density gauge that contained a 1.48 GBq (40 mCi) Am-Be source and a 0.37 GBq (10 mCi) Cs-137 source. The gauge was last seen on 2/19/2020 at the end of work in McKinney, Texas. It was locked in a box in the back of a truck that was driven to Euless, Texas, where it stayed until 2/24/2020. The truck was driven to a job site in Richardson, Texas, on 2/24/2020. At that point, the employee realized that the locks were missing and the gauge had been stolen. The Euless Police were notified. The Texas Department of State Health Services received a phone call on 6/17/2020 stating that a moisture/density gauge had been found in a load of scrap metal from a large recycling steel mill in Midlothian, Texas. The serial number identified this as the stolen gauge. The testing company was notified on 6/18/2020, retrieved the gauge, and transported it to one of the manufacturer's locations in Arlington, Texas, for disposal. The gauge had apparently been through a shredder and the outer casing was gone. The identification tags were in place on the shielding, though there was some damage. The Am-Be source was in its shielded position. The Cs-137 source rod had broken off and the rod, with the source still attached to the end, was separated from the shielding. The Cs-137 source did not appear to be damaged or compromised. After the Cs-137 source was inserted into the shield, a survey indicated normal radiation levels. Based on the information from the steel mill and the testing company’s RSO, no radiation exposures at the steel mill would exceed any regulatory limit. The manufacturer will perform leak testing. Corrective actions included terminating the employment of the involved employee, writing a new procedure, and providing training to technicians. Investigation will continue to determine if there may have been any radiation exposure at the recycler that exceeded limits. This event was classified as an EQP and LAS event.

Item Number 200081 - An electrical generating station reported inadequate source shielding on a fixed level gauge that contained a 925 MBq (25 mCi) Cs-137 source. The incident was discovered during an inspection on 2/20/2020. Radiation measurements ranged from approximately 0.15 to 0.45 mSv/hour (15 to 45 mrem/hour) at one foot from the back of the source holder cap. The gauge was located 11.5 feet off the ground in an area with no stationed personnel or foot traffic. Station personnel immediately removed the gauge from service, secured the area, and contacted the manufacturer to repair or replace the gauge. The Pennsylvania Bureau of Radiation Protection performed a reactive inspection. On 3/3/2020, a technician from a radiological services company inspected and surveyed the gauge, performed a leak test, packaged/secured the gauge in a Type A steel drum, and shipped it to his company’s facility. The leak test revealed negative results. The gauge was dismantled, the source holder/capsule was removed, and the source was temporarily stored in a depleted uranium shield. It was determined that the source holder and capsule had dislodged from their bracket/housing, resulting in the elevated radiation levels. Degradation of the bracket was most likely caused by long-term vibration and physical wear. Although internal wear was apparent, the shutter mechanism functioned as designed. The source capsule was to be transferred for disposal as part of a consolidated shipment scheduled for April 2020.

Item Number 200141 - A recycling company in Ft. Worth, Texas, sent a cargo container of scrap metal to Korea, which was rejected upon arrival due to radioactivity. U.S. Customs and Border Protection seized the container when it arrived at the Terminal Island docks in San Pedro, California, on 1/19/2020. The California Health and Human Services Agency was contacted on 1/21/2020 and responded to the site the next day. Using a Fluke 451B, the initial radiation survey of the container measured 680 µR/hour at the surface, with 420 µR/hour at one foot, and 160 µR/hour at three feet (background was 10 µR/hour). The radionuclide was identified as Cs-137. DOT Exemption CA-TX-20-004 was issued and the container was returned to the recycling company on 2/18/2020. A Texas Department of State Health Services (TDSHS) inspector responded to the recycling facility on 2/19/2020. The inspector surveyed the material as it was being unloaded from the container. The source of radiation was a small steel cylinder that looked like the source from a moisture/density gauge. Pictures were sent to a gauge manufacturer who stated that the source appeared to be from one of their moisture/density gauges. TDSHS shipped the source to the manufacturer on 3/13/2020. The manufacturer confirmed that the Cs-137 source was indeed from one of their moisture/density gauges and identified the owner. The associated Am-Be source was not found. This event was classified as an EQP and LAS event.

Item Number 200163 - A construction materials testing company reported that a moisture/density gauge was crushed by a bulldozer at a construction site in Edison, New Jersey, on 4/2/2020. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source. The New Jersey Department of Environmental Protection and Environmental Protection Agency Radiological Assistance were notified and dispatched personnel to the scene. Visual inspection indicated that the source rod was intact but detached from the gauge. The Am-Be source inside the gauge appeared to be intact. The majority of the base of the gauge was intact, but the face plate and plastic between the base and face plate was shattered. A radiation survey identified 67.9 mR/hour near the source and 41 mR/hour around the perimeter of the gauge. The gauge was transported back to the company's facility. The sources were not breached. Corrective actions included additional training for the involved employee.

Item Number 200179 - A university reported that an electrical fire (burning smell and visible smoke) occurred while using a self-contained irradiator on 4/7/2020. The irradiator contained 994.87 GBq (26.87 Ci) of Cs-137 and was located in a shielded room. The aperture electronic opening and closing mechanism malfunctioned while the aperture was open. Personnel immediately deenergized the irradiator and notified department management. Using portable shielding and lead apron body protection, personnel subsequently closed the device attenuator, which significantly reduced radiation exposure rates. The closure took less than five seconds. Radiation levels while approaching the unit from the backside were less than 25 mR/hour. The aperture remained stuck partially open. The area was securely locked, the door alarm was activated, and signs were posted to remind everyone not to use the irradiator. The dosimeters of the personnel involved read less than 0.01 mSv (1 mrem). There was no exposure rate above background in any area accessible by members of the public. The irradiator manufacturer was contacted to discuss repair options.

Item Number 200214 - A medical event resulted from a high dose rate afterloader failure during a breast cancer treatment on 5/5/2020. The afterloader contained a 318.2 GBq (8.6 Ci) Ir-192 source. An error was noted when the source was returning from treating channel 3 of 10. The source retracted fully into the safe position. Staff reset the unit and rebooted. Treatment resumed with channel 4, however upon returning the source to safe position the unit experienced another fault. This time the source did not fully retract. Staff attempted two emergency-stop procedures, both of which failed. Staff manually retracted the source after approximately two to four minutes from receiving the channel 4 error. The patient was quickly disconnected from the catheter, everyone was immediately removed, and the room was secured. The patient and involved personnel were surveyed after the incident and all readings were at background. The manufacturer's service technicians removed the source from the afterloader on 5/6/2020. It appeared that the source became stuck approximately 4 to 5 inches from the park position (inside the afterloader, but outside the shielded safe). Dosimetry badges were sent for emergency processing. The preliminary

dosimetry report indicated that three staff members received minor radiation exposures. The Pennsylvania Department of Environmental Protection will perform a reactive inspection. This event was classified as an EQP and MED event.

Item Number 200217 - A construction materials testing company reported that a moisture/density gauge was struck by a bulldozer at a jobsite in Matteson, Illinois, on 5/11/2020. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source. The gauge user was not injured, but the gauge was destroyed. The source rod remained intact and both sources were identified and recovered into a lead drum. Using a Geiger Muller survey meter, the external exposure rate was 400 μR/hour on the outside of the drum. The sources were transported back to the company's facility. The manufacturer was contacted for advice and instructions for returning the sources. Illinois Emergency Management Agency inspectors met with the company on 5/12/2020 and verified that both sources had been recovered and did not appear to be ruptured. A gross wipe test performed on both sources indicated that the sources were not leaking. Quantitative leak tests were received from the manufacturer and confirmed the sources were not leaking. A verbal recount of the incident indicated there was little concern of an occupational radiation exposure exceeding regulatory limits. Regardless, the gauge user's dosimetry report was obtained and reviewed. Instruction was given on proper packaging and return of the destroyed gauge to Troxler. The original Type A package was used and the inspectors performed surface and one meter dose rate readings to ensure proper labeling and DOT compliance. Confirmation of receipt by the manufacturer was received on 6/3/2020.

Item Number 200236 - A sheet metal manufacturer reported that a fixed nuclear gauge was damaged on a process line on 5/30/2020. The 37 GBq (1 Ci) Am-241 source was dislodged from the gauge housing and fell onto surrounding equipment in an unshielded position. Workers immediately withdrew and fire/safety and security staff cordoned off the area. Illinois Emergency Management Agency staff responded the same day to assist in securing the source, assess for removable contamination, and evaluate any potential exposures to workers. Agency staff evaluated airflow, took surveys, and established a recovery plan with site security/safety and the RSO. Exposure rates were approximately 170 mR/hour at one foot and background at the cordoned off boundary. Remote handling tools were used to place the source into a pig. The source was then secured within the company's radioactive material storage safe. Wipes were taken of the area, the damaged gauge housing, and the process equipment. No removable radioactive contamination was identified. Discussions concerning worker proximity and time in place after the source became dislodged indicated that no radiation exposures exceeded regulatory limits. Leak test results received on 6/11/2020 indicated that the source was not leaking. The licensee returned the source and gauge to the manufacturer for repair/disposal.

Item Number 200253 - An environmental remediation company reported the discovery of a fixed nuclear gauge at a scrap yard on 6/15/2020. The gauge contained a Cs-137 source with an estimated activity of 222 MBq (6 mCi). The gauge shutter appeared to be stuck open or missing. Exposure rates on contact with the area where the shutter should have been were 407 mR/hour, with 23.5 mR/hour at one foot. No loose contamination was detected. No identifying information was visible on the gauge. A scrap yard representative stated that they were cleaning up a section of the yard and a load of dirt containing the gauge alarmed the radiation monitors on the way out of the facility. He said that the gauge could have been there for more than 10 years. The origin of the gauge is unknown. The remediation company packaged the gauge and took possession of it for disposal. The Ohio Department of Health performed a survey of the scrap yard on 6/16/2020. No other radioactive material was detected. This event was classified as an EQP and LAS event.

Item Number 200272 - A construction materials testing company reported that a moisture/density gauge was damaged at a jobsite in Romulus, Michigan, on 7/7/2020. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and 0.163 GBq (4.4 mCi) Cs-137 source. While the source rod was extended into the ground, the technician stepped about 10 feet away and turned his back to the gauge. A pickup truck attempting to leave the work area turned to avoid the technician and struck the gauge. Although the

pickup truck was traveling at a slow speed, its bumper struck the gauge index rod with enough force to bend the source rod at the base of the gauge. The technician was unable to retract the Cs-137 source into the shielded position. The RSO was contacted and the area was secured. Despite instructions to not move the gauge, the technician attempted to straighten the source rod by moving the gauge to a concrete pad and striking the source rod with a hammer. This resulted in splitting open the threaded portion of the source rod end cap. The broken end cap (containing the source) was ejected by a small retaining spring and landed a few feet away on the concrete pad. Using foot-long pliers, the technician placed the end cap in a plastic cylinder used for concrete samples. The RSO arrived at the scene approximately 45 minutes later. Following guidance from a service company, the RSO placed the end cap in a bucket with sand. After securing the bucket and gauge in a vehicle, the RSO surveyed the area and found no evidence of residual contamination at the job site. The bucket and gauge were transported to the company's office in Plymouth, Michigan, where a leak test was performed with negative results. The source was later transferred to a lead pig. On 8/21/2020, the gauge and source were transferred to the manufacturer for disposal. NRC inspectors determined that the technician likely received no more than 0.05 mSv (5 mrem) of whole-body exposure. Corrective actions included personnel training on radiation safety and the safe use of gauges. Emergency procedures were revised to address expectations for the safe use of gauges in normal and abnormal situations.

Item Number 200285 - A radioactive source vendor reported that a high dose rate brachytherapy source was damaged while in transit with a common carrier. The 413.99 GBq (11.189 Ci) Ir-192 source was being shipped to a cancer treatment center in Everett, Washington. The source was returned to the vendor because the drive cable was found damaged and twisted upon receipt. The transport container had been damaged. The source was found one inch higher than its designated shielded transportation position. The return survey identified an exposure rate of 80 mR/hour at the surface and 4 mR/hour at one meter. The container had been shipped with an exposure rate of 31 mR/hour at the surface and 0.9 mR/hour at one meter. This event was classified as an EQP and TRS event.

Item Number 200350 - During a routine inspection of a construction materials testing company on 8/18/2020, the Arizona Department of Health Services discovered that a moisture/density gauge appeared to be missing its Cs-137 source rod shutter. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source. While performing a survey of the gauge, inspectors recorded an exposure rate of 175 mR/hour over the shutter opening while the handle was in its locked position.

2.7.3 Events Recently Added to NMED That Occurred Prior to FY20

Eight EQP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events
None

Events of Interest
Item Number 190364 - A fire at a chemical manufacturing company consumed three small outbuildings on 8/2/2019, one of which contained six obsolete benchtop x-ray fluorescence spectrometry units. Two of the devices were recovered by the company immediately after the fire, but they were extensively damaged. The remaining four devices were destroyed. Each device contained three radioactive sources, including two Fe-55 sources and one Cm-244 source. The original activities of the Fe-55 sources were 740 MBq (20 mCi) and 222 kBq (6 µCi). The original activities of the Cm-244 sources were 1,110 MBq (30 mCi). A decontamination company was contracted to remediate the site. They arrived on 12/10/2019 and recovered three discrete pieces of radioactive material in the fire debris. All radioactive material was containerized and stored at the site. An ash pile containing radioactive remains was stored on poly

sheeting at the fire location pending disposition. All radioactive material was properly disposed of. Survey results demonstrated that any residual activity left in the area was well below requirements for unrestricted use. The cause of the fire was believed to have been an electrical short.

Item Number 200064 - During a routine inspection on 2/6/2020, the Illinois Emergency Management Agency discovered that a flooding event occurred on 2/22/2019 at a panoramic irradiator facility in Libertyville, Illinois. The irradiator contained 142,000 TBq (3,830,804 Ci) of Co-60. A coupler on a two-inch sprinkler line in the maze of the cell broke during processing. The cell consequently flooded and began to flood the warehouse. An emergency console stop was executed and both source racks submerged at 1821. The pool high water alarm was tripped. Within the next 80 minutes the smoke detector, exhaust fans, collision bar, inside roof plug, low air pressure, high temperature, main panel communications, loss of 110 VAC, and 24 VDC faults were logged. At 2024, both source racks were moved back up. The deionizer radiation monitor alarmed. A number of alarms and faults continued until approximately 1121 on 2/23/2019. Up to four inches of water covered the pool and the warehouse. The fire department shut off the water main feeding the sprinklers. Inspection findings indicated that high and low water monitors, as well as the deionizer radiation monitor, were disabled because of the flooding. Dosimetry was evaluated and no unusual exposures were noted. Staff interviews indicated that security systems were not impacted. The affected equipment was repaired. The facility transitioned to a manually initiated dry fire suppression system.

2.8 Transportation

2.8.1 Ten-Year Data

Figure 8 displays the annual number and trend of TRS events that occurred during the 10-year period. The trend analysis determined that the Total and NRC-regulated events represent statistically significant decreasing trends (indicated by the trend lines). However, the Agreement State-regulated events do not represent a statistically significant trend (indicated by the absence of a trend line).

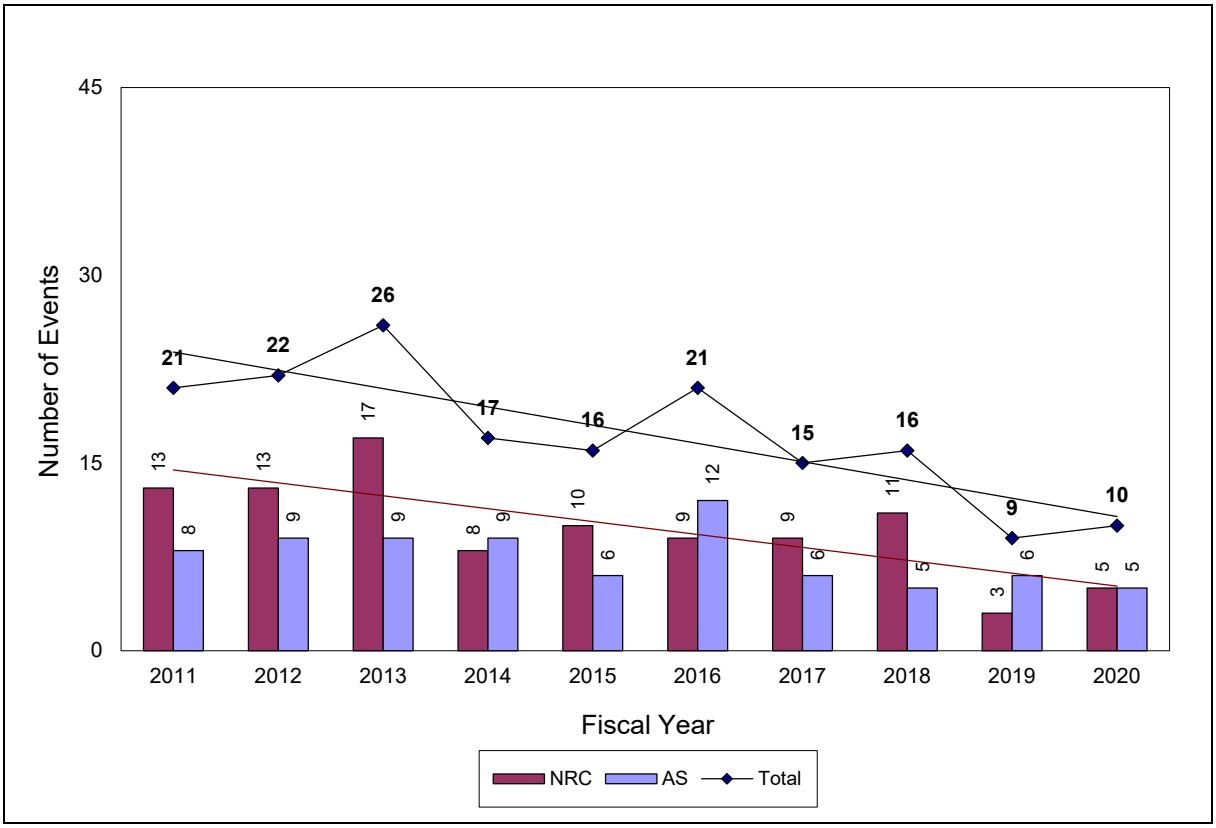

Figure 8. Transportation Events (173 total)

It is not possible to discern the significance of TRS events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.8.2 FY20 Data

Ten TRS events occurred in FY20, two of which were considered significant.

Significant Events

Item Number 200068 - A radiography services company reported abnormally high radiation levels on a package containing a radiography exposure device shipped from a vendor in Houston, Texas. The device contained a 4.19 TBq (113.3 Ci) Ir-192 source. The radiography services company's RSO picked up the shipment at a common carrier's facility in Amarillo, Texas, on 2/11/2020 and placed it in the back of his pickup truck. The RSO then surveyed the package. Radiation readings were 40 mR/hour on three sides and 400 mR/hour on the fourth side. The RSO confirmed the reading with a second meter. The RSO contacted a consultant and was directed to tape a self-reading dosimeter to the side of the package. After 10 minutes, the dosimeter read 0.5 mSv (50 mrem). The RSO contacted his manager who then brought

two additional meters to the location. The highest reading found in these surveys was 900 mR/hour. The RSO moved the truck/device to a remote area at the common carrier's facility and built a barrier. The vendor was contacted and provided pictures showing how the device was packaged. With a power screwdriver, the RSO removed the top of the package and inspected the device. The RSO found that both the shutter and cap were open. The RSO closed the shutter and cap using a remote handling tool. The exposure rate then decreased to 40 mR/hour. The RSO transported the device to the company's storage location. Investigation conducted at the vendor's facility revealed no indications of improper procedures for loading, packaging, and shipping devices. The vendor evaluated the device and found no malfunctioning parts or mechanisms. The vendor modified their procedures to include installing a wire tamper seal to secure the front port cap as recommended by the manufacturer. Radiation exposure assessments performed at the vendor suggest that no individuals were exposed in excess of limits during transit. The radiography services company stated that the only significant exposure was to the RSO at 0.03 mSv (3 mrem) to the left hand and 0.05 mSv (5 mrem) whole body.

Item Number 200220 - A nuclear services company received a package (10-gallon drum) with high radiation levels from a construction materials company on 5/11/2020. The drum contained a gauge with a 3.7 GBq (100 mCi) Cs-137 source. The receipt survey identified 34 mSv/hour (3.4 rem/hour) on contact, 2.4 mSv/hour (240 mrem/hour) at 12 inches, and 0.18 mSv/hour (18 mrem/hour) at 3.3 feet. The package had been shipped as UN2915, Radioactive Material Type A, with Yellow-II labeling, and a Transport Index of 0.1. The common carrier and construction materials company were notified. The Pennsylvania Department of Environmental Protection will perform a reactive inspection.

Events of Interest

Item Number 200285 - A radioactive source vendor reported that a high dose rate brachytherapy source was damaged while in transit with a common carrier. The 413.99 GBq (11.189 Ci) Ir-192 source was being shipped to a cancer treatment center in Everett, Washington. The source was returned to the vendor because the drive cable was found damaged and twisted upon receipt. The transport container had been damaged. The source was found one inch higher than its designated shielded transportation position. The return survey identified an exposure rate of 80 mR/hour at the surface and 4 mR/hour at one meter. The container had been shipped with an exposure rate of 31 mR/hour at the surface and 0.9 mR/hour at one meter. This event was classified as an EQP and TRS event.

2.8.3 Events Recently Added to NMED That Occurred Prior to FY20

Two TRS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events

None

Events of Interest

None

2.9 Other

2.9.1 Ten-Year Data

Figure 10 displays the annual number of OTH events that occurred during the 10-year period. Because OTH events do not fit a defined criterion that ensures consistency within the data, trending analysis is not performed on this data.

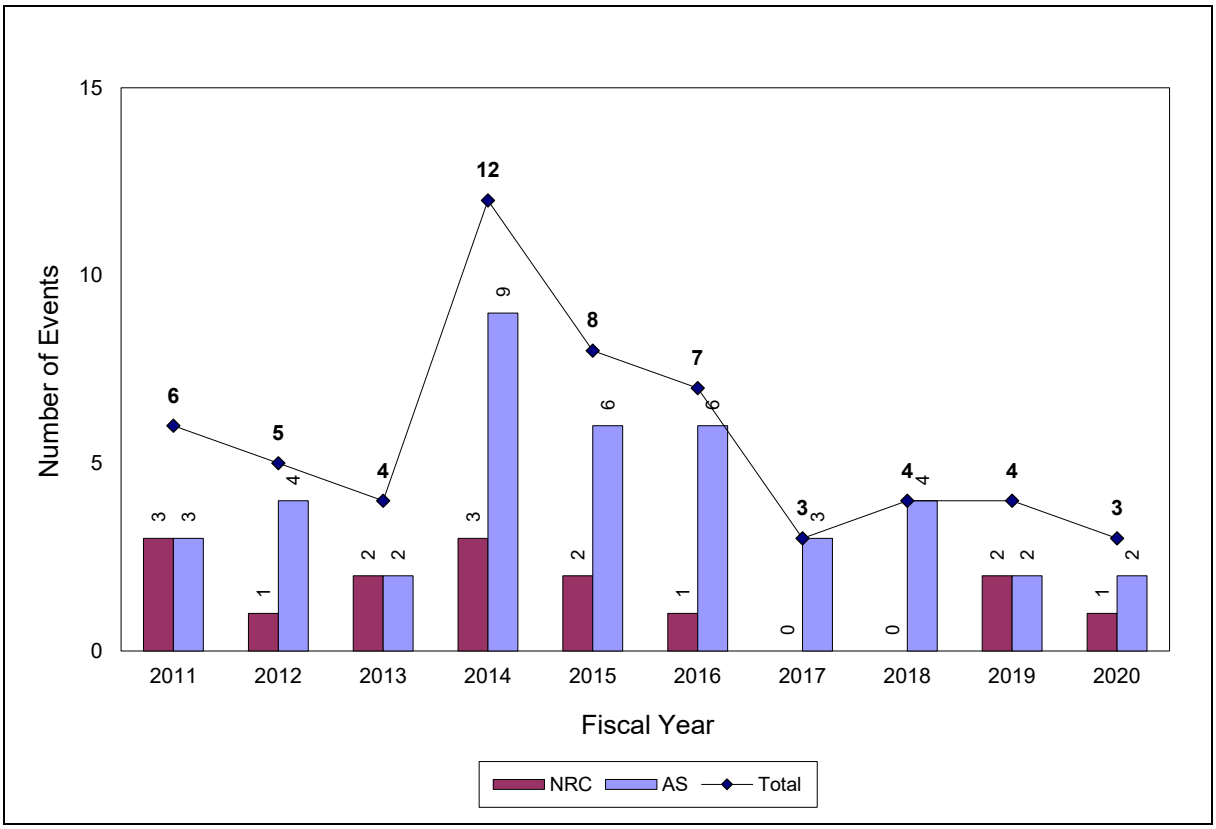

Figure 9. Other Events (56 total)

It is not possible to discern the significance of OTH events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.9.2 FY20 Data

Three OTH events occurred in FY20, one of which was considered significant.

Significant Events

Item Number 200051 - An embryo/fetus received a radiation dose when a patient who was unknowingly pregnant received an Lu-177 dotatate therapy treatment on 1/9/2020. A serum pregnancy test administered to the patient on 1/3/2020 was negative. On 1/9/2020, prior to the therapy treatment, the patient reported that there was no chance of being pregnant. The patient was then administered 7.53 GBq (203.5 mCi) of Lu-177 dotatate. This was the second of four treatments, with the first treatment occurring on 11/13/2019. On 1/28/2020, the patient notified her medical oncologist that she was pregnant. The medical oncologist informed the treating physician the same day. On 1/29/2020, the treating physician contacted the patient and learned that the possible date of conception was 1/3, 1/4, or 1/5/2020. The dose to the embryo/fetus was calculated to be 14.3 cSv (rem). The treating physician reviewed the radiation

effects with the patient on 1/31/2020, stating that there was no expected increased risk of fetal death or anatomical malformations at delivery. The patient terminated the pregnancy on 2/18/2020 and scheduled her next treatment. To prevent recurrence, the hospital revised their policy to require a negative serum pregnancy test within 48 hours prior to treatment. The NRC performed a special inspection on 2/5/2020 to review the event. A medical consultant concurred with the hospital's evaluation of the event, including the dose calculation. This event was classified as a potential Abnormal Occurrence.

Events of Interest
Item 200300 - Two contract employees (members of the public) received a radiation exposure while working inside a vessel at a plastics manufacturing company on 5/9/2020. The vessel was 20 feet tall, 8 feet in diameter, and equipped with three fixed nuclear gauges. Each gauge contained a 52.762 GBq (1.426 Ci) Cs-137 source. The company failed to close and lock the source shutters prior to entry. The employees entered the vessel from an access port in the top portion of the vessel and climbed down a rope ladder hanging in the center of the vessel. They passed two of the sources at a distance of four feet while descending to the bottom of the vessel. Because the gauges had exposure ports with 45-degree collimators, the employees were primarily exposed only to the lowest source, which was mounted approximately 6.7 feet above the vessel's bottom platform where the employees stood. One employee was in the vessel for 13 minutes and the other employee for 28 minutes. The company estimated that one employee received 0.06 mSv (6 mrem) and the other employee received 0.13 mSv (13 mrem). Corrective actions included procedure modifications and providing additional training to personnel. The Texas Department of State Health Services investigated. Their exposure calculations were higher than the company's, but still less than 1 mSv (100 mrem).

2.9.3 Events Recently Added to NMED That Occurred Prior to FY20

No OTH events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events
None

Events of Interest
None

Appendix A

Event Type Descriptions and Criteria

Appendix A
Event Type Descriptions and Criteria

The NMED events covered by this report are divided into the following categories based on the event reporting requirements defined in 10 CFR. Note that the tables in this appendix do not contain the full text of the applicable CFRs.

Lost/Abandoned/Stolen Material (LAS)

The LAS event category includes those events where licensed radioactive material is lost or found, abandoned or discovered, and stolen or recovered. The radioactive material involved can be sealed or unsealed material, specifically or generally licensed, exempt or non-exempt quantities, involve a licensee or a non-licensee, and can be found anywhere. Abandoned well logging sources are included in this category.

NMED LAS reportable events are those that meet the reporting requirements of 10 CFR Part 20.2201. Events that do not meet the 20.2201 reporting requirement thresholds are captured as not-reportable LAS events. Additionally, LAS events involving non-Atomic Energy Act material are entered into NMED as not-reportable events.

All reportable LAS events will be coded as one of the following reporting requirements. For events involving more than one source, the decision of 10 × or 1,000 × the 10 CFR Part 20 Appendix C quantity is based on the aggregate quantity of licensed material.

Table A-1. Primary LAS Reporting Requirements

Primary LAS Reporting Requirements	Reporting Requirement Summary
20.2201(a)(1)(i)	Aggregate activity ≥ 1,000 × 10 CFR Part 20 Appendix C quantity
20.2201(a)(1)(ii)	Aggregate activity > 10 and < 1,000 × 10 CFR Part 20 Appendix C quantity
39.77(d)	Irretrievable well logging source

The following additional (secondary) CFRs will be added as applicable. This should occur infrequently. For the 10 CFR 37 requirements, the event will instead be coded as OTH if there was no actual theft, sabotage, or diversion of Category 1 or 2 quantities of radioactive material.

Table A-2. Secondary LAS Reporting Requirements

Secondary LAS Reporting Requirements	Reporting Requirement Summary
30.55(c)	Theft/diversion of 10 Ci (or 100 Ci per year) of H 3 (not generally licensed).
37.57(a)	Unauthorized entry resulted in actual ~~or attempted~~ theft, sabotage, or diversion of a category 1 or category 2 quantity of material.
37.57(b)	Suspicious activity related to possible theft, sabotage, or diversion of a category 1 or category 2 quantity of material
37.81(a)	A shipment of category 1 quantities of material is lost or missing.
37.81(b)	A shipment of category 2 quantities of material is lost or missing.
37.81(c)	Actual ~~or attempted~~ theft or diversion (or related suspicious activities) of a shipment of category 1 quantities of material.
37.81(d)	Actual ~~or attempted~~ theft or diversion (or related suspicious activities) of a shipment of category 2 quantities of material.
37.81(e)	Recovery of any lost or missing shipment of category 1 quantities of material.
37.81(f)	Recovery of any lost or missing shipment of category 2 quantities of material.

39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.
40.64(c)(1)	Theft/diversion of 15 lb (or 150 lb per year) of source material (uranium or thorium).
73.71(a)(1)	Lost shipment of any SNM.
73.App G(I)(a)(1)	Actual or attempted theft or unlawful diversion of SNM.
74.11(a)	Loss, theft or unlawful diversion (actual or attempted) of SNM or the unauthorized production of enriched uranium.
76.120(a)(2)	Loss, other than normal operating loss, of special nuclear material.
76.120(a)(3)	Actual or attempted theft or unlawful diversion of special nuclear material.
150.16(b)(1)	Actual or attempted theft or unlawful diversion of SNM.
150.17(c)(1)	Attempted theft or unlawful diversion of more than 6.8 kg (15 lb) of Uranium or Thorium at any one time or more than 68 kg (150 lb) in any one calendar year.
150.19(c)	Theft/diversion of 10 Ci (or 100 Ci per year) of H-3 (not generally licensed). Note: This requirement is just like 30.55(c), but applies to Agreement States and offshore waters.

Medical (MED)

MED events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-3. MED Reporting Requirements

MED Reporting Requirements	Reporting Requirement Summary
35.3045(a)(1)(i)(A)	Total dose delivered that differs from the prescribed dose by 20% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(i)(B)	Total dosage delivered that differs from the prescribed dosage by 20% or more or falls outside the prescribed range; and results in a dose that differs from prescribed by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(i)(C)	Fractionated dose delivered that differs from the prescribed dose for a single fraction by 50% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(A)	Administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(B)	Administration of a radioactive drug containing byproduct material by the wrong route of administration that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(C)	Administration of a dose or dosage to the wrong individual or human research subject that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(D)	Administration of a dose or dosage delivered by the wrong mode of treatment that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(E)	Leaking sealed source that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(iii)	Dose to the skin, organ, or tissue, other than the treatment site, that exceeds by 0.5 Sv (50 rem) or more and 50% or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.
35.3045(a)(2)(i)	For permanent implant brachytherapy, the total source strength administered differs by 20% or more from the total source strength documented in the post-implant portion of the written directive, excluding sources that were implanted in the correct site but migrated outside of the treatment site.
35.3045(a)(2)(ii)	For permanent implant brachytherapy, the total source strength administered outside of the treatment site exceeds 20% of the total source strength documented in the post-implant portion of the written directive, excluding sources that were implanted in the correct site but migrated outside of the treatment site.
35.3045(a)(2)(iii)(A)	For permanent implant brachytherapy, an administration that includes the wrong radionuclide.
35.3045(a)(2)(iii)(B)	– For permanent implant brachytherapy, an administration that includes the wrong individual or research subject.
35.3045(a)(2)(iii)(C)	For permanent implant brachytherapy, an administration that includes sealed sources implanted directly into a location discontiguous from the treatment site, as documented in the post-implant portion of the written directive.
35.3045(a)(2)(iii)(D)	For permanent implant brachytherapy, an administration that includes a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

35.3045(b)	Event resulting from patient intervention in which the administration of byproduct material or radiation from byproduct material results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Events are not considered MED events if they involve:

- Only a linear accelerator,
- Doses administered in accordance with a written directive (even if the directive is in error), or
- Patient intervention, unless the event results in unintended permanent functional damage to an organ or physiological system.

Events are considered MED events if, for example, a linear accelerator is used for therapy by mistake instead of a teletherapy unit or a teletherapy unit instead of a linear accelerator.

For purposes of determining whether to categorize an event as MED or EXP, MED events occur to patients only (i.e., those being administered a medical procedure). For example, if a patient receives too much dose during a procedure, the event would be categorized as MED rather than EXP. However, radiation exposure received from a cause other than the patient's medical procedure may be categorized as EXP.

Radiation Overexposure (EXP)

EXP events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-4. EXP Reporting Requirements

EXP Reporting Requirements	Reporting Requirement Summary
20.2202(a)(1)(i)	An individual received a total effective dose equivalent of 25 rem (0.25 Sv) or more.
20.2202(a)(1)(ii)	An individual received a lens dose equivalent of 75 rem (0.75 Sv) or more.
20.2202(a)(1)(iii)	An individual received a shallow-dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more.
20.2202(b)(1)(i)	Loss of control of material causing or threatening to cause an individual to receive a total effective dose equivalent exceeding 5 rem (0.05 Sv) in a period of 24 hours.
20.2202(b)(1)(ii)	Loss of control of material causing or threatening to cause an individual to receive an eye dose equivalent exceeding 15 rem (0.15 Sv) in a period of 24 hours.
20.2202(b)(1)(iii)	Loss of control of material causing or threatening to cause an individual to receive a shallow-dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv) in a period of 24 hours.
20.2203(a)(2)(i)	Doses in excess of the occupational dose limits for adults in 20.1201.
20.2203(a)(2)(ii)	Doses in excess of the occupational dose limits for a minor in 20.1207.
20.2203(a)(2)(iii)	Doses in excess of the limits for an embryo/fetus of a declared pregnant woman in 20.1208.
20.2203(a)(2)(iv)	Doses in excess of the limits for an individual member of the public in 20.1301.
20.2203(a)(2)(v)	Doses in excess of any applicable limit in the license.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.

The EXP event category includes all regulatory overexposures of radiation workers or exposures of members of the public to radiation. The overexposure can be external or internal and can be whole body, extremity, skin, lens of the eye, or internal dose. When the overexposure involves multiple individuals or an individual with multiple overexposure types (such as whole body and extremity), the different types of overexposures are entered separately. Note that dosimeters record exposure if improperly stored near a radiation source and, depending on the type of dosimeter, may react as though they are in a radiation field when exposed to heat or humidity.

It is NRC policy to classify only those events that positively involve a personnel overexposure, and not just a dosimeter exposure, as reportable EXP events. For example, either the licensee does not contest the personnel overexposure, or in cases where the licensee does contest the overexposure, the State or NRC determines the event to be personnel overexposure.

EXP limits do not apply to patients receiving medical procedures.

Release of Licensed Material or Contamination (RLM)

RLM events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-5. RLM Reporting Requirements

RLM Reporting Requirements	Reporting Requirement Summary
20.2202(a)(2)	Release of radioactive material, inside or outside of a restricted area, so that had an individual been present for 24 hours, the individual could have received an intake 5 times the ALI.
20.2202(b)(2)	Release of material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of 1 ALI.
20.2203(a)(2)(vi)	Doses in excess of the ALARA constraints for air emissions established under 20.1101(d).
20.2203(a)(3)(i)	Radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in the license.
20.2203(a)(3)(ii)	Radiation or concentrations of radioactive material in an unrestricted area in excess of 10 times any applicable limit set forth in Part 20 or in the license.
20.2203(a)(4)	Levels of radiation or releases of radioactive material in excess of the standards in 40 CFR Part 190, or of license conditions related to those standards.
30.50(a) 40.60(a) 70.50(a) 76.120(b)	Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of material that could exceed regulatory limits.
30.50(b)(1) 40.60(b)(1) 70.50(b)(1) 76.120(c)(1)	Unplanned contamination event that requires access to be restricted for > 24 hours, involves > 5 times the lowest ALI, and has access restricted for a reason other than to allow isotopes with a half-life of < 24 hours to decay.
30.50(b)(3) 40.60(b)(3) 70.50(b)(3) 76.120(c)(3)	Event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.
50.72(b)(3)(xii) 72.75(c)(3)	Event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

The RLM event category includes two types of events. The first type is a radioactive release to air or water exceeding the 10 CFR Part 20 Appendix B annual limit on intake (ALI). The second type of RLM event involves contamination events such as a radioactive spill outside of work areas, removable contamination found on equipment, or material tracked around a laboratory such that additional radiological control measures had to be implemented. This category does not include spills inside of laboratory hoods, radiopharmaceutical dose preparation areas, or hot cells where radioactive work routinely requires cleanup or changing of absorbent paper after the performance of a task. Should there be multiple release types (e.g., surface, air, water, or person) or areas of contamination associated with the release, this information is entered individually.

Leaking Sealed Source (LKS)

LKS events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-6. LKS Reporting Requirements

LKS Reporting Requirements	Type of Source
31.5(c)(5)	Generally licensed
34.27(d)	Radiography
35.67(e)	Medical
39.35(d)(1)	Well logging (leaking)
39.77(a)	Well logging (ruptured)
30.50(b)(2)	All other sources

The NRC requires that most sealed sources be periodically leak tested to verify that the material is still sealed and that the source is still considered safe to use without contamination controls, including protective clothing or gloves. Sources are generally exempt from leak testing under the following conditions [see 10 CFR Part 31.5(c)(2), 34.27(c), 35.67(f), and 39.35(e)]:

- Sources containing only gaseous radioactive material (like H-3, Kr-85, etc.),
- Sources containing licensed material with a half-life of 30 days or less,
- Sources containing <= 100 μCi of other beta and/or gamma emitting material,
- Sources containing <= 10 μCi of alpha emitting material,
- Sources held in storage in the original shipping container prior to initial installation,
- Seeds of Ir-192 encased in nylon ribbon, or
- Sources in storage and not in use (must be leak tested prior to use or transfer).

A source is considered leaking if a leak test can detect greater than 0.005 μCi of removable radioactive material. The leaking source is then removed from service, disposed of or returned to the manufacturer for repair, and a report is sent to the NRC or Agreement State with the details of the leaking source.

For regulatory reporting purposes, a leaking source is generally considered a failed device under 10 CFR Part 30. Therefore, in most cases an LKS event is also coded as an EQP event. An exception is the Ni-63 foil source, which is coded as only an LKS event.

Equipment (EQP)

EQP events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-7. EQP Reporting Requirements

EQP Reporting Requirements	Reporting Requirement Summary
21.21(d)(1)(i)	A failure to comply or a defect affecting the construction or operation of a facility or an activity that is subject to licensing requirements.
21.21(d)(1)(ii)	A failure to comply or a defect affecting a basic component that is supplied for a facility or an activity that is subject to licensing requirements.
30.50(a) 40.60(a) 70.50(a) 76.120(b)	Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of material that could exceed regulatory limits.
30.50(b)(2) 40.60(b)(2) 70.50(b)(2) 72.75(d)(1) 76.120(c)(2)	Equipment is disabled or fails to function as designed.
30.50(b)(4) 40.60(b)(4) 70.50(b)(4) 76.120(c)(4)	Unplanned fire or explosion that damages any licensed material or any device, container, or equipment containing licensed material.
31.5(c)(5)	Actual or indicated failure to shielding, the on-off mechanism or indicator, or upon the detection 0.005 uCi or more of removable radioactive material.
34.101(a)(1)	Unintentional disconnection of the radiographic source assembly from the control cable.
34.101(a)(2)	Inability to retract and secure the radiographic source assembly to its fully shielded position.
34.101(a)(3)	Failure of any radiographic component (critical to the safe operation of the device) to properly perform its intended function.
35.3204	Eluate exceeding the permissible concentration of Mo-99, Sr-82, and Sr-85, as listed in 35.204(a), at the time of generator elution; more than 0.15 kBq Mo-99 per MBq Tc-99m, more than 0.02 kBq Sr-82 per MBq Rb-82 chloride, or more than 0.2 kBq Sr-85 per MBq Rb-82 chloride.
36.83(a)(1)	An irradiator source stuck in an unshielded position.
36.83(a)(2)	Fire or explosion in an irradiator radiation room.
36.83(a)(3)	Damage to the irradiator source racks.
36.83(a)(4)	Failure of the irradiator cable or drive mechanism used to move the source racks.
36.83(a)(5)	Inoperability of the irradiator access control system.
36.83(a)(6)	Detection of irradiator source by the product exit monitor.
36.83(a)(7)	Detection of irradiator radioactive contamination attributable to licensed radioactive material.
36.83(a)(8)	Structural damage to the irradiator pool liner or walls.
36.83(a)(9)	Abnormal water loss or leakage from the irradiator source storage pool.
36.83(a)(10)	Irradiator pool water conductivity exceeding 100 microsiemens per centimeter.
39.77(a)	Ruptured well logging sealed source.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.

72.75(c)(1)	Defect in any spent fuel, HLW, or reactor-related GTCC waste storage structure, system, or component that is important to safety.
72.75(c)(2)	Significant reduction in the effectiveness of any spent fuel, HLW, or reactor-related GTCC waste storage confinement system during use.
72.242(d)	Design or fabrication deficiency for any spent fuel storage cask delivered to a licensee which affects the ability of components important to safety to perform their safety function.

The EQP event category includes all types of radiological equipment problems, including generally licensed device problems covered in 10 CFR Part 31; radiography equipment problems covered in 10 CFR Part 34; irradiator problems covered in 10 CFR Part 36; well logging problems covered in 10 CFR Part 39, and other types of equipment covered in 10 CFR Part 30, 40, 70, and 76. EQP events are defined as the failure of, or a defect in, any piece of equipment that either contains licensed radioactive materials as an integral part, or whose function is to interact with such materials.

Transportation (TRS)

TRS events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-8. TRS Reporting Requirements

TRS Reporting Requirements	Reporting Requirement Summary
20.1906(d)(1)	Transported package exceeds removable surface contamination limits.
20.1906(d)(2)	Transported package exceeds external radiation limits.
71.5	Transportation of licensed material.
71.95(a)(1)	Significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use.
71.95(a)(2)	Defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.
71.95(a)(3)	Conditions of approval in the Certificate of Compliance were not observed in making a shipment.
71.95(b)	Conditions in the Certificate of Compliance were not followed during a shipment.

Other (OTH)

The OTH event category includes the following types of events:

1. Doses to an embryo/fetus or nursing child reportable per 10 CFR Part 35.3047. Note that these events are not MED events (reportable per 10 CFR Part 35.3045).
2. Dose in an unrestricted area in excess of 2 mrem in an hour, but no individual received a dose in excess of limits (if a dose in excess of limits is received, the event is an EXP event).
3. 10 CFR 37 events that do not result in the actual theft, sabotage, or diversion of Category 1 or 2 quantities of radioactive material. Otherwise, the event is as an LAS event.
4. Reportable events that do not specifically fit into one of the previous event types.

For items 1-3 above, OTH events are determined and coded per the 10 CFR reporting requirements listed below. Due to the nature of item 4 above, other reporting requirements may also be used.

Table A-9. OTH Reporting Requirements

OTH Reporting Requirements	Reporting Requirement Summary
20.2203(a)(2)(iv)	Dose in an unrestricted area in excess of 2 mrem in an hour, but no dose received in excess of limits.
35.3047(a)	Dose to an embryo/fetus greater than 50 mSv (5 rem) DE from administration of byproduct material or radiation from byproduct material to a pregnant individual unless specifically approved, in advance, by the authorized user.
35.3047(b)(1)	Dose to a nursing child greater than 50 mSv (5 rem) TEDE resulting from an administration of byproduct material to a breast-feeding individual.
35.3047(b)(2)	Dose to a nursing child resulting in unintended permanent functional damage to an organ or physiological system, as determined by a physician, resulting from an administration of byproduct material to a breast-feeding individual.
37.57(a)	Unauthorized entry resulted in ~~actual or~~ attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of material.
37.57(b)	Suspicious activity related to possible theft, sabotage, or diversion of a category 1 or category 2 quantity of material
37.81(c)	~~Actual or~~ attempted theft or diversion (or related suspicious activities) of a shipment of category 1 quantities of material.
37.81(d)	~~Actual or~~ attempted theft or diversion (or related suspicious activities) of a shipment of category 2 quantities of material.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.

Appendix B

Statistical Trending Methodology

Appendix B
Statistical Trending Methodology

General

The following is a general discussion of statistical trending techniques.

A common approach to the statistical analysis of trend is based on regression methods. In particular, it is often the case that a relationship exists between the values assumed by a pair of variables. For example, if x is time (in years), and y is the rate of events per year, then we could use regression methods to study whether there is a relationship between time and event rate.

Regardless of the application, it is standard practice to refer to x as the independent variable and y as the dependent variable. Another common term for the dependent variable is "response variable," and the terms covariant and explanatory variable are sometimes used for the independent variable. Also, it is typical with regression modeling that the independent variable can be measured with little or no error, but the dependent variable involves a random error. Consequently, even if there is a deterministic functional relationship between the two variables, when data pairs (x_1, y_1), (x_2, y_2),..., (x_n, y_n) are plotted, the points will not coincide exactly with the function, but instead will tend to be scattered. Such a plot is called a scatter diagram and shows the variation in the data. The plots in this report are bar charts containing the same information.

Fitting a Straight Line to Data

Consider a linear function

$$f(x) = \alpha + \beta x \tag{B-1}$$

where α and β are unknown parameters. A common model is that y is the sum of a linear function of the form (1) and a random error term, e. Standard results on estimation and inference about the parameters of the model assume that e is a normally distributed random variable with mean 0 and constant (but unknown) variance, σ^2. These assumptions mean that:

- Each yi is an observed value of a random quantity that is normally distributed [with mean f(xi)], and
- All the observations yi are of variables with a common variance, σ2.

The y_i are also assumed to be observations of random quantities that are independent of each other.

Under these conditions, the usual approach to estimating the unknown parameters α and β is the method of least squares (LS). In this method, α and β are selected so that the sum of the squares of the vertical distances between the data points and the fitted line is as small as possible. The LS method leads to the estimates

$$\hat{\beta} = \frac{\sum_{i=1}^{n}(x_i - \bar{x})y_i}{\sum_{i=1}^{n}(x_i - \bar{x})^2} \text{ and} \tag{B-2}$$

$$\hat{\alpha} = \bar{y} - \hat{\beta}\bar{x}\,, \tag{B-3}$$

where $\bar{x}$ and $\bar{y}$ are arithmetic averages. The estimated LS regression line is then

$$\hat{y} = \hat{\alpha} - \hat{\beta}x\,, \tag{B-4}$$

and an estimate of σ is

$$s = \sqrt{\frac{\sum_{i=1}^{n} (y_i - \hat{y}_i)^2}{n-2}} \,. \tag{B-5}$$

Testing for Trend

A trend exists whenever the true slope, β, is not zero. We start the analysis with the idea that β is zero, and then ask whether the data tell us otherwise. Two quantities computed from the data are used in this assessment. The first, the *error sum of squares* (SSE), appears in the numerator of s. It is defined as

$$SSE = \sum_{i=1}^{n} (y_i - \hat{y}_i)^2 \,. \tag{B-6}$$

This quantity is the number that is minimized in order to find the estimates of α and β. The differences being squared in SSE represent random variations that remain after the linear fitting process. The second quantity is the *regression sum of squares* (SSR), defined by the following equation

$$SSR = \sum_{i=1}^{n} (\hat{y}_i - \bar{y})^2 \,. \tag{B-7}$$

Note that SSR looks at deviations between the fitted line and the default notion that the data are constant and have no slope.

One can show by algebra that

$$SSE + SSR = SST \,, \tag{B-8}$$

where the *total sum of the squares* (SST), is defined as

$$SST = \sum_{i=1}^{n} (y_i - \bar{y})^2 \,. \tag{B-9}$$

SST measures the overall variation in the data. It is the numerator that would be used to estimate the variance in a sample from a normally-distributed random variable, where all the data in the sample have the same distribution (and thus no trend). This variance measures "random variation" in such a sample.

In the framework of the linear function (1), the regression's effectiveness is measured by the *SSR* term defined above. When it is small, the fitted curve will not differ very much from the horizontal line $y = \bar{y}$. *SSE* will be approximately equal to *SST*, and, from the data, both *SSE* and *SST* will be estimates of mere random variation. In this case, the data does not provide evidence that β is different from zero.

On the other hand, if the y values tend to vary linearly with respect to the independent variable, x, then some of the variation in the y values can be attributed to this dependence on x. Since *SSR* assesses the difference between the least squares predictions of the y values and the arithmetic mean, $\bar{y}$, it is a measure of the variation which is "explained" by the linear relationship. When the slope of the fitted line is large, more of these differences will tend to be large, resulting in a large value of *SSR*.

In the equation, $SST = SSE + SSR$, the total variation is partitioned into two parts, the variation due to random error and the variation due to the linear relationship. The fraction of the total variation that is due to the linear relationship is called the coefficient of determination, or r^2, and is defined by:

$$r^2 = \frac{SSR}{SST} \,. \tag{B-10}$$

r^2 is a fraction that varies from 0 to 1. It will be near 0 if most of the variation is due to randomness, and it will be near 1 if most of the variation is due to the linear relationship.

The closeness to 1 needed for the data to show that the slope is not zero depends on the number of data points. If the dependent data are independent, normally-distributed at each x, with constant variance, and no trend, then the quantity, F, defined by

$$F = \frac{(n-2)\,r^2}{1-r^2} \tag{B-11}$$

can be shown to have an F distribution with degrees of freedom 1 and $n - 2$, where n is the number of data points. When the data satisfy the assumptions except that there is a significant trend, r^2 will be closer to 1 and the computed F statistic will be much larger. Specifically, if the computed F exceeds the upper fifth percentile of the F distribution with 1 and $n - 2$ degrees of freedom, we infer that the data contain evidence that β is not zero, at the 5% level of significance. In this case, we reject the null hypothesis that $\beta = 0$ and conclude that a statistically significant trend exists, with 95% confidence.

As an example, for an assumed set of data fit to the linear model, assume the $r^2 = 0.9369$ and that n is 13. Then the calculated F is 163.3. The upper 95th percentile of the $F(1,11)$ distribution is 4.84. Since 163.3 far exceeds the upper 95th F percentile, the linear model is statistically significant. In this example, the data show that it would be very unlikely for a trend not to exist. The linear model explains too much of the variation in the data for a trend not to exist.

Applying the Model to the NMED Data

The method described above was applied for each category of NMED event data, for the overall NMED data, and for additional subgroups of data when trends were found in the overall data. When the calculated F exceeded the 95th percentile, the trend line was shown on the graph and identified as being statistically significant.

In future reports, methods slightly different than that explained above could be employed because the NMED data in many cases does not follow the assumptions listed above. In particular, three considerations apply.

- The data are counts, and thus are discrete rather than being normally distributed. This problem is most pronounced when the counts are relatively low or sparse. Also, normally-distributed data in general can be negative, but the counts are always greater than or equal to zero.
- Variations in counts tend to increase as the counts increase. If the events occur at random, with a constant occurrence rate in a particular year or quarter, then the variance of the count for that year or quarter is equal to the mean or average for that year or quarter. Thus, the assumption of a constant variance for the data in each year may not apply.
- Finally, more than one count can be associated with a single reported incident in a single event category. This situation would occur, for example, if several pieces of equipment fail in an event or if several types of overexposure occur. In these cases, the data are not independent.

One way to address the first two concerns is to identify the number of licensees in various NMED categories and study the event occurrence rates rather than the counts. The rates are more likely to come from a continuum and might have a more constant variance.

Taking logarithms of the counts and then applying the LS method avoids the problem of possible negative trend lines. The resulting models can be converted back to the scale of the counts after the regression line is identified. In the scale of the counts, the resulting trend, if any, has a slight curvature.

Weighted regression is a method similar to the LS method described above, but it compensates explicitly for the effect of the different variances from year to year.

Another approach that deals with the first two concerns is to apply regression methods that have been designed specifically for counts. Poisson regression, for example, is based on the idea that the data in each time period are counts observed from a Poisson distribution, with an occurrence rate that is described by the model. Given occurrence rates in each time period, and independent counts, the probability of seeing the observed data is easily computed by multiplying the occurrence probabilities for the individual time periods. The slope and intercept parameter estimates are selected so that the model maximizes the resulting "likelihood function."

The third issue may have little effect on the results of a trend analysis, as long as there are many counts with relatively few occurring in clumps, no trends in the occurrence of clumps, and no large clumps of counts coming from a single occurrence report. The best way to address the dependence issue is to identify and remove the duplicate counts prior to the trend analysis.

Appendix C

IAEA Radionuclide Categorization

Appendix C
IAEA Radionuclide Categorization

Table C-1 lists the radionuclides that this report uses to determine the significance for events involving the loss, abandonment, or theft of radioactive sources. This list is derived from the IAEA *Code of Conduct on the Safety and Security of Radioactive Sources (2004)* and from IAEA Safety Guide RS-G-1.9, *Categorization of Radioactive Sources*. Based on the amount of radioactivity involved, the radionuclides are grouped into five categories, with Category 1 being the most hazardous. These categories may be summarized as follows (derived from IAEA Safety Guide RS-G-1.9, *Categorization of Radioactive Sources*):

Category 1: **Extremely dangerous.** These sources could cause permanent injury within a few minutes if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from a few minutes to an hour.

Category 2: **Very dangerous.** These sources could cause permanent injury within minutes to hours if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from hours to days.

Category 3: **Dangerous.** These sources could cause permanent injury within hours if handled. Doses could possibly (but unlikely) be fatal to someone in close proximity to an unshielded source for periods ranging from days to weeks.

Category 4: **Unlikely to be dangerous.** These sources would not cause permanent injury, although delayed health effects are possible. Doses could possibly (but unlikely) cause temporary injury to someone in close proximity to an unshielded source for a period of many weeks.

Category 5: **Most unlikely to be dangerous.** These sources would not cause permanent injury.

Table C-1. IAEA Code of Conduct Category 1 through 5 Radionuclide Activity Thresholds

Radionuclide	Category 1		Category 2		Category 3		Category 4		Category 5	
	TBq	Ci [1]	TBq	Ci [1]	TBq	Ci [1]	TBq	Ci [1]	TBq	Ci [1]
Am-241	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Am-241/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Cf-252	20	541	0.2	5.4	0.02	0.54	0.0002	0.0054	1.0e-08	2.7e-07
Cm-244	50	1,352	0.5	13.5	0.05	1.35	0.0005	0.0135	1.0e-08	2.7e-07
Co-60	30	811	0.3	8.1	0.03	0.81	0.0003	0.0081	1.0e-07	2.7e-06
Cs-137	100	2,703	1.0	27.0	0.10	2.70	0.001	0.0270	1.0e-08	2.7e-07
Gd-153	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-05	2.7e-04
Ir-192	80	2,162	0.8	21.6	0.08	2.16	0.0008	0.0216	1.0e-08	2.7e-07
Pm-147	40,000	1,081,200	400.0	10,812.0	40.00	1,081.20	0.4	10.8120	1.0e-05	2.7e-04
Pu-238	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Pu-239/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Ra-226	40	1,081	0.4	10.8	0.04	1.08	0.0004	0.0108	1.0e-08	2.7e-07
Se-75	200	5,406	2.0	54.1	0.20	5.41	0.002	0.0541	1.0e-06	2.7e-05
Sr-90 (Y-90)	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-08	2.7e-07
Tm-170	20,000	540,600	200.0	5,406.0	20.00	540.60	0.2	5.4060	1.0e-06	2.7e-05
Yb-169	300	8,109	3.0	81.1	0.30	8.11	0.003	0.0811	1.0e-05	2.7e-04

Notes

1. The primary values are given in TeraBequerel (TBq). Curie (Ci) values are provided for practical usefulness only and are rounded after conversion.

Appendix D

Revision of Data

Appendix D
Revision of Data

The NMED is a dynamic database with new reports and revisions to previous reports being added on a continuing basis. This activity can result in additions or subtractions to data that was published in previous issues of this report. Numerical changes in NMED numbers can result from several different types of technical changes to coded data. The most common types of changes to database records are:

- Record additions due to late reporting
- Record additions or subtractions due to changes in event type
- Changes between fiscal years due to event date changes on individual events
- Record additions or subtractions due to changes in event reportability
- Record additions or subtractions due to reclassifying a single combined event as multiple individual events (or vice versa)
- Record deletions due to duplicated records or NRC direction

Figures D-1 through D-9 below display the changes in the data published in the previous annual report. A positive value indicates that records were added and a negative value indicates that records were removed.

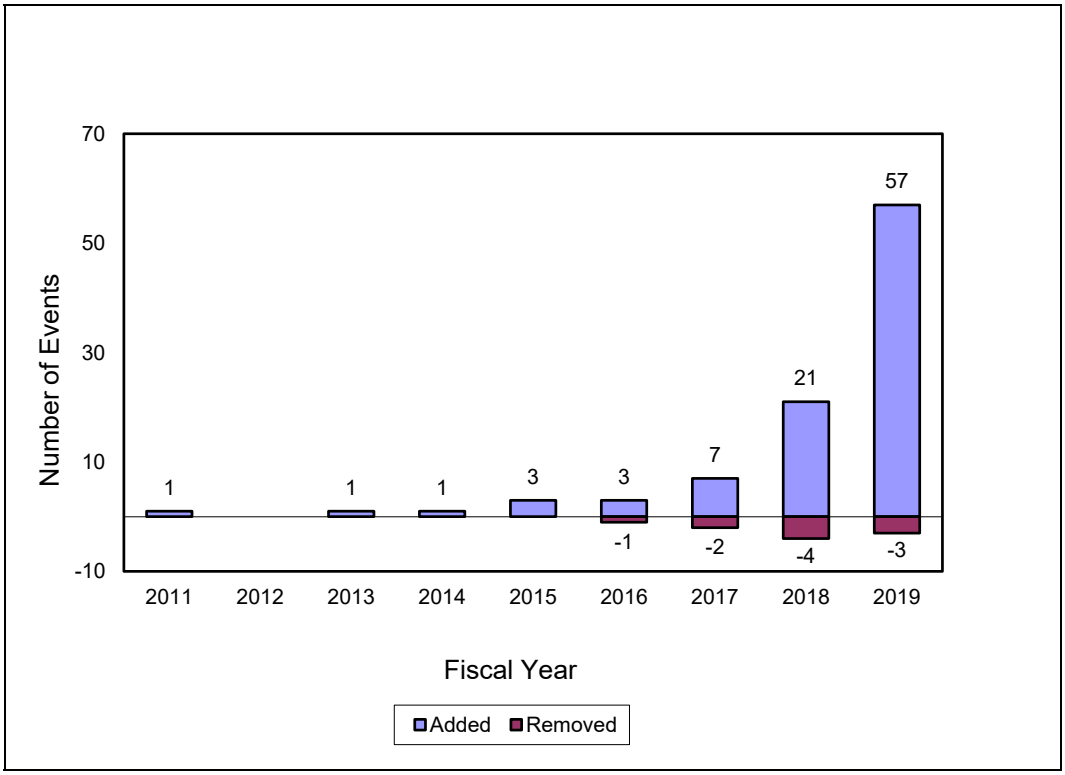

Figure D-1. Changes to All NMED Event Data

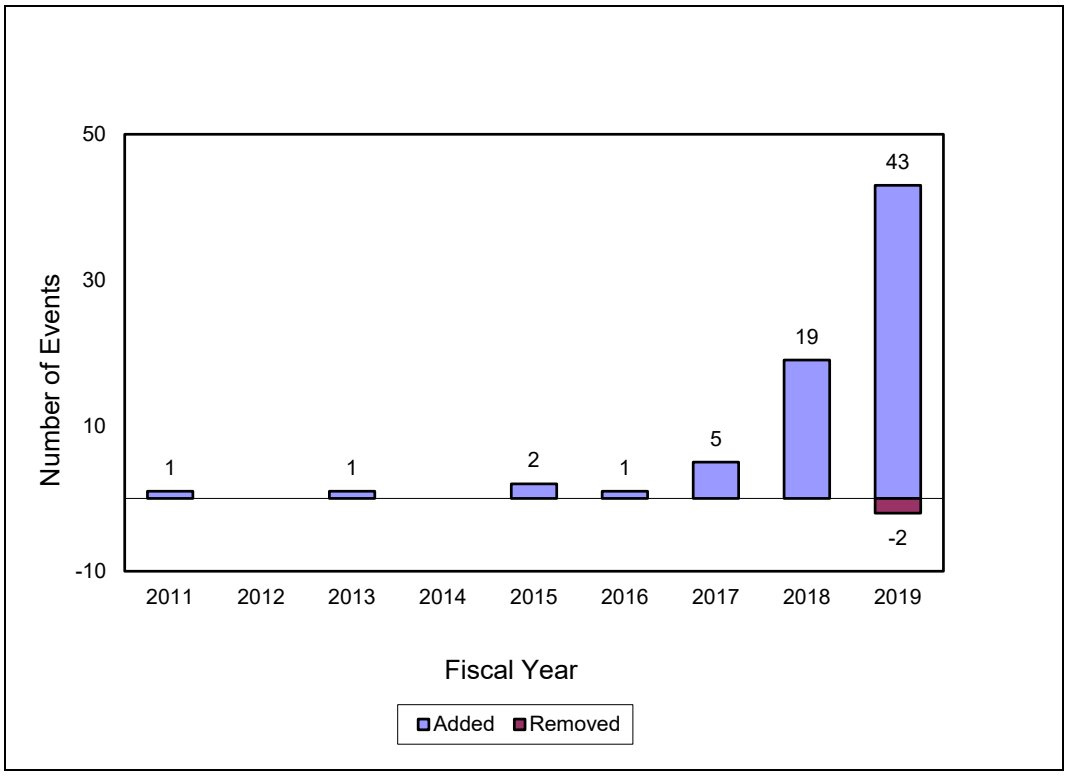

Figure D-2. Changes to LAS Data

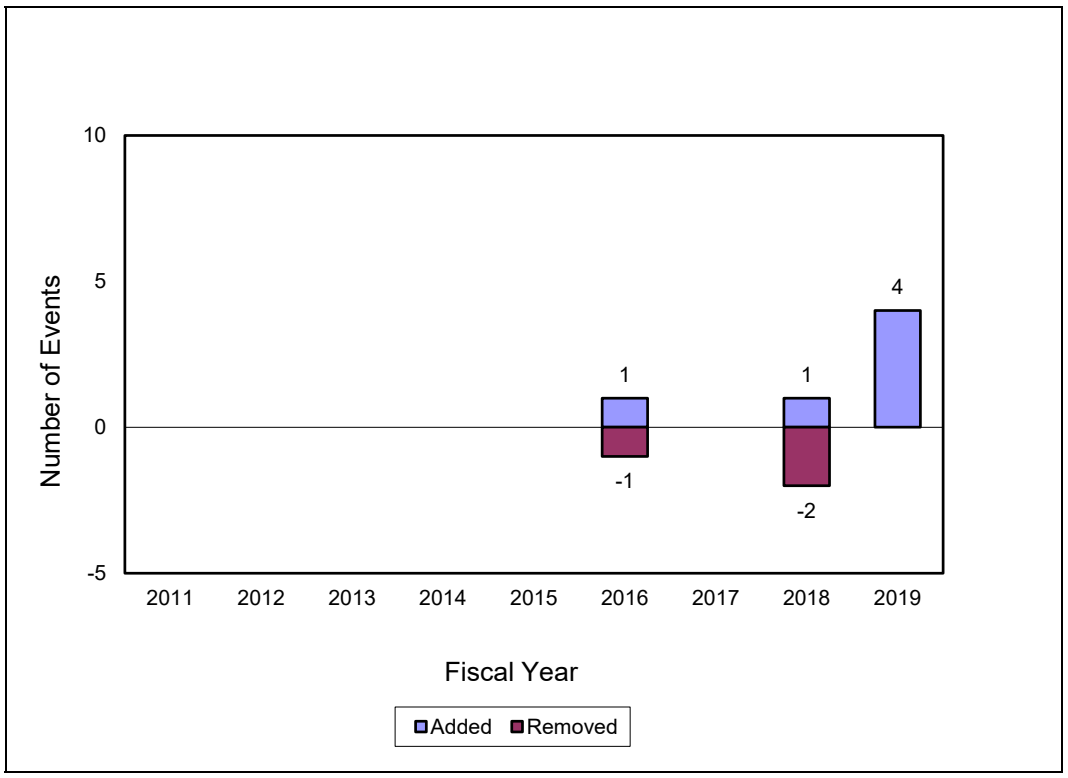

Figure D-3. Changes to MED Data

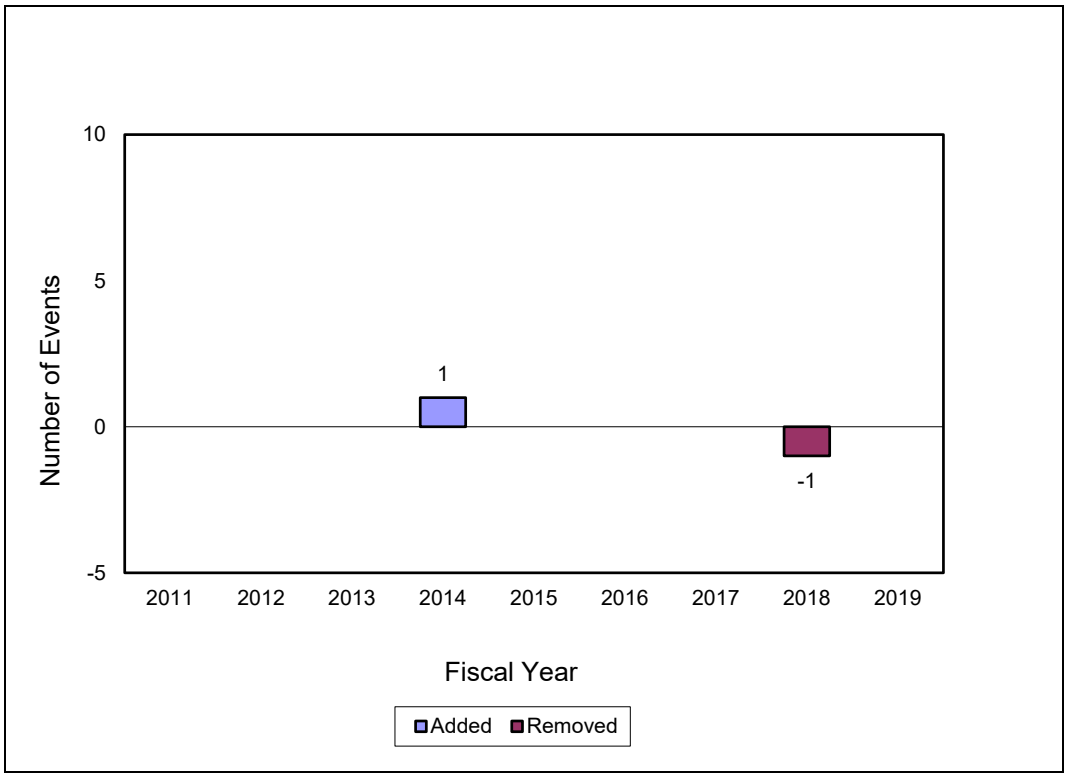

Figure D-4. Changes to EXP Data

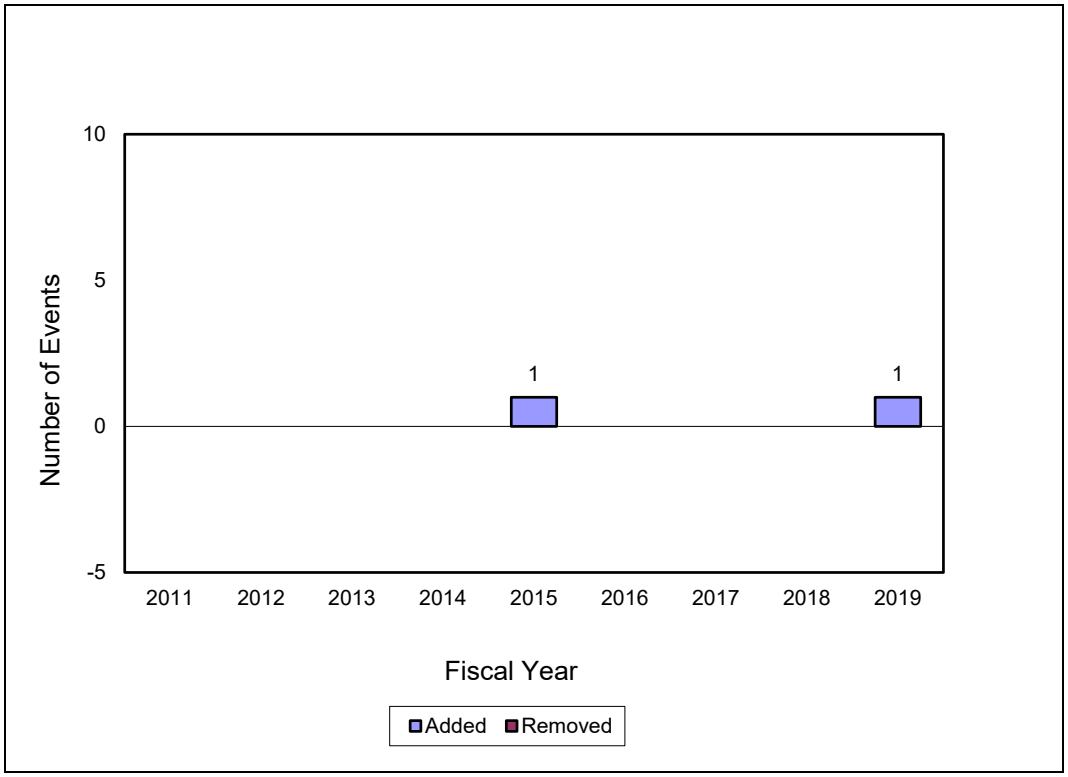

Figure D-5. Changes to RLM Data

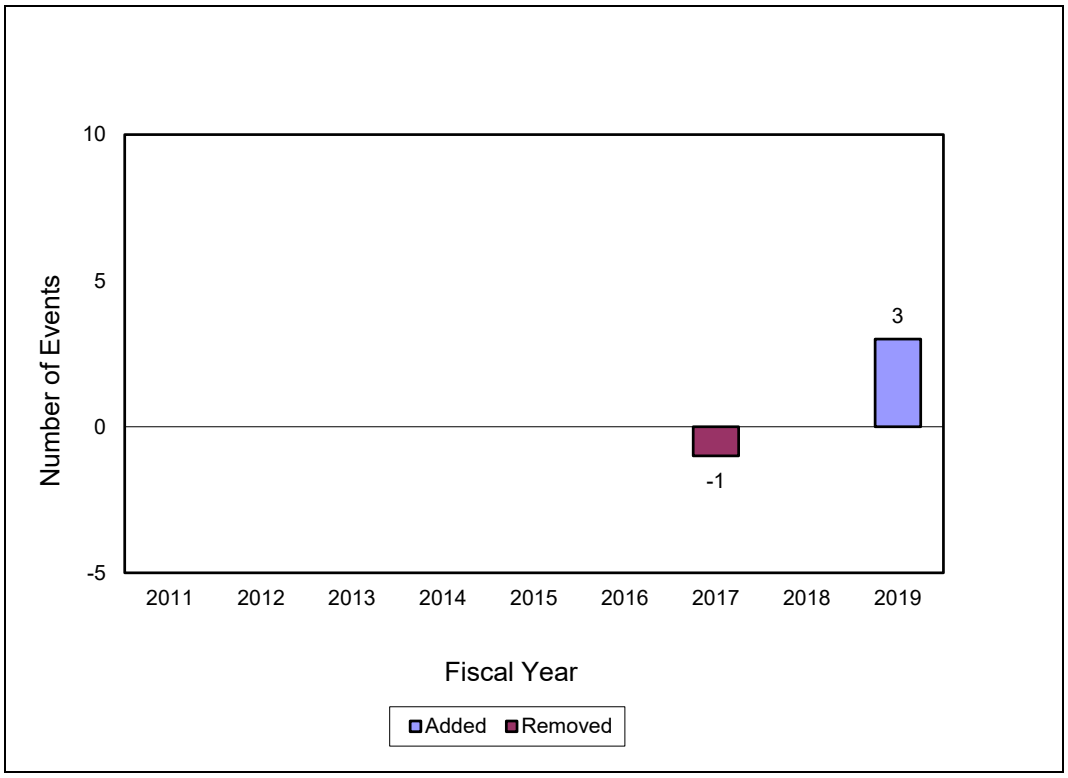

Figure D-6. Changes to LKS Data

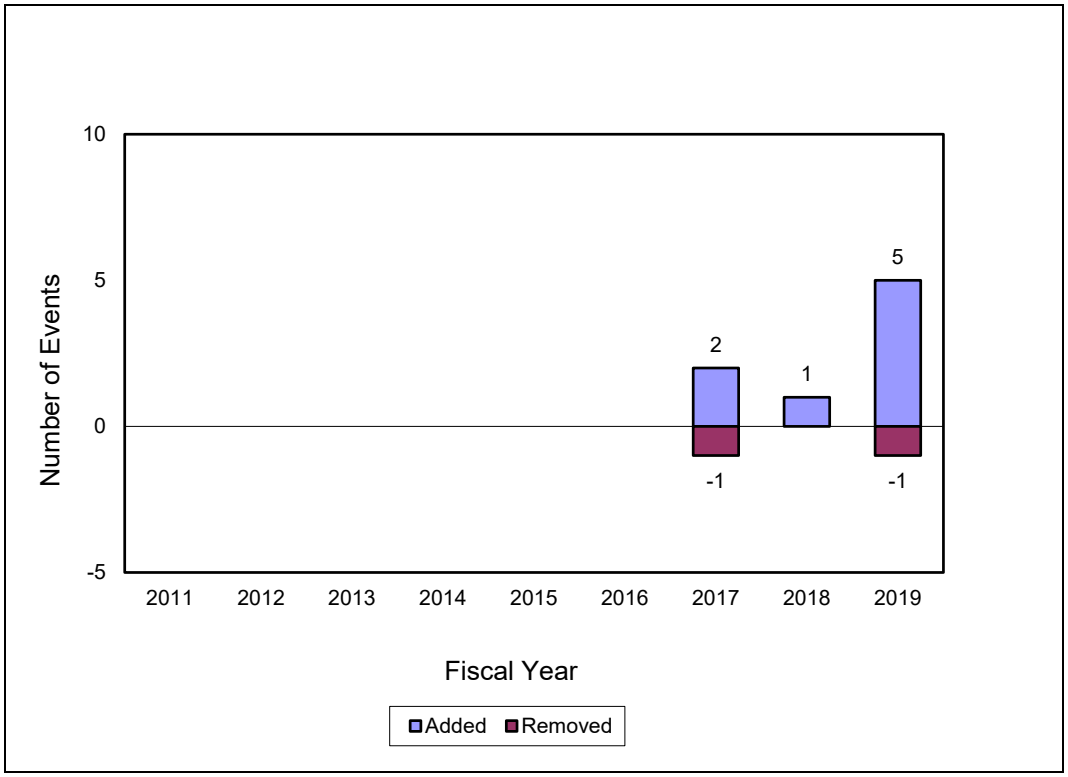

Figure D-7. Changes to EQP Data

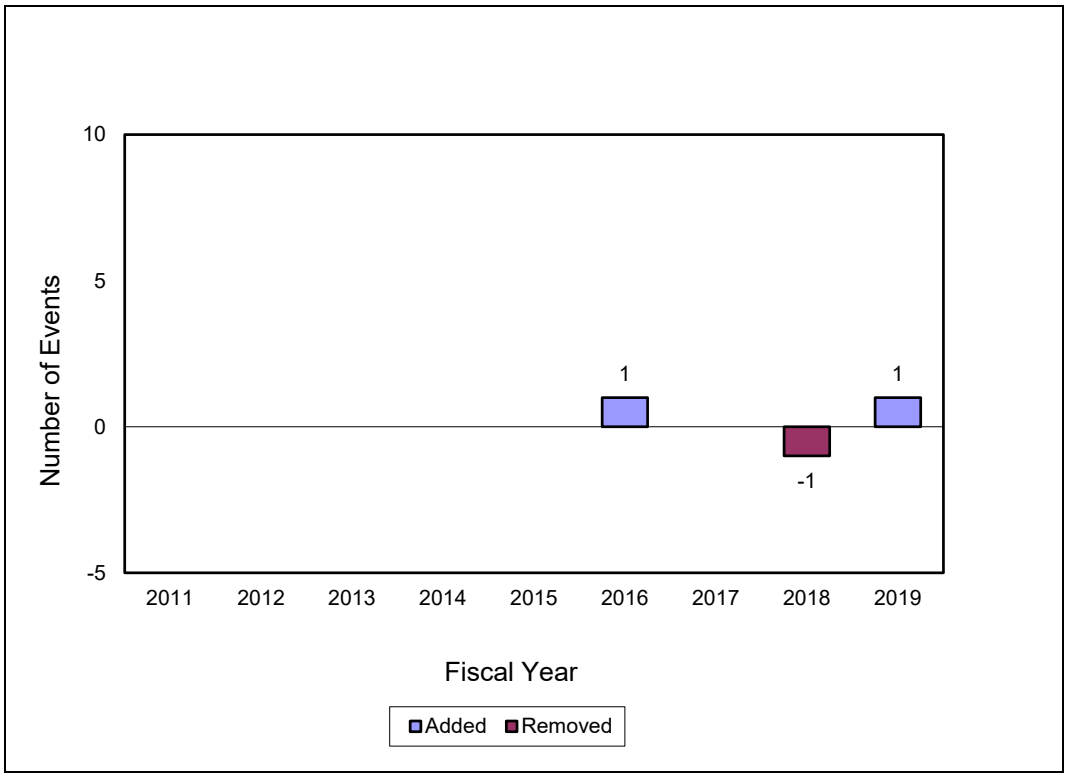

Figure D-8. Changes to TRS Data

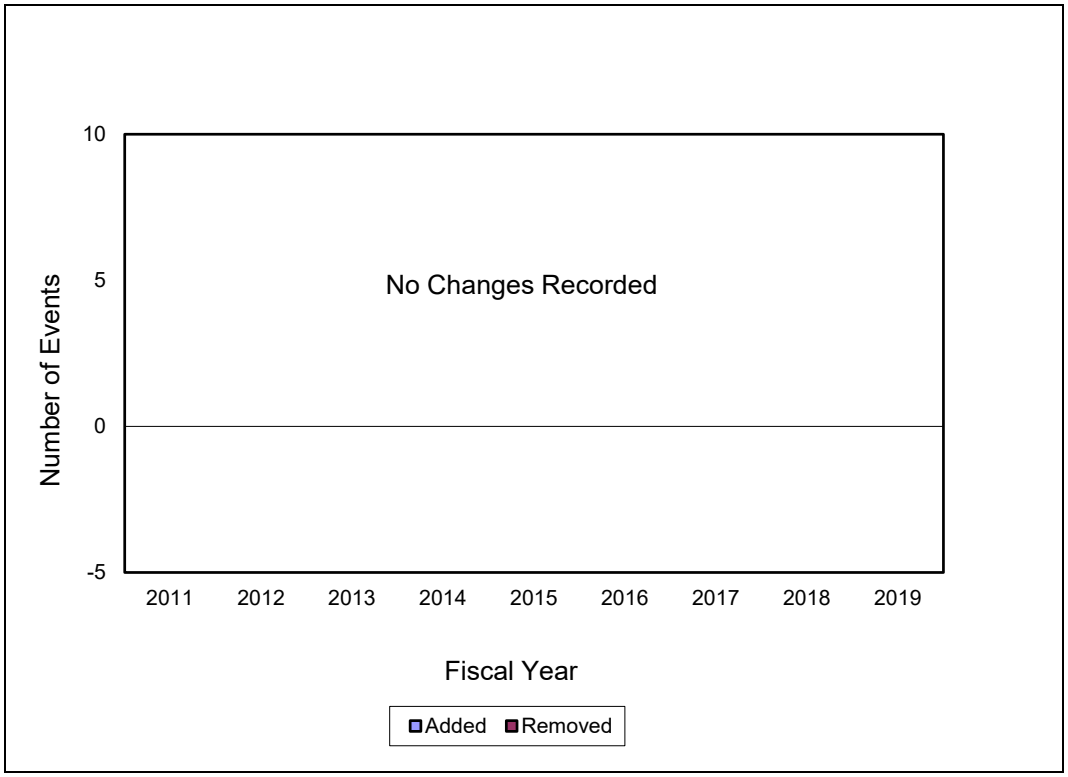

Figure D-9. Changes to OTH Data