January 2018



# Nuclear Material Events Database

# **Annual Report**

Fiscal Year 2017

Prepared for the U.S. Nuclear Regulatory Commission by the Idaho National Laboratory (INL/LTD-18-44380)

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## **Nuclear Material Events Database**

# **Annual Report**

## Fiscal Year 2017

Thomas W. Smith, INL Dante C. Huntsman, INL Robert L. Sant, INL

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Idaho National Laboratory Risk Assessment and Management Services Idaho Falls, Idaho 83415

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### 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
ARRA	Arizona Radiation Regulatory Agency
CFR	Code of Federal Regulations
СТ	computed tomography
DDE	deep dose equivalent
DE	dose equivalent
DOT	Department of Transportation
EDE	effective dose equivalent
EQP	Equipment
EXP	Radiation Overexposure
FBI	Federal Bureau of Investigation
FBRC	Florida Bureau of Radiation Control
FY	fiscal year
GPS	global positioning system
GTCC	greater than class C
HDR	high dose rate
HEPA	high efficiency particulate air
HLW	high-level waste
IAEA	International Atomic Energy Agency
IEMA	Illinois Emergency Management Agency
INL	Idaho National Laboratory
IT	information technology
LAS	Lost/Abandoned/Stolen Material
LKS	Leaking Sealed Source
LS	least squares
MDRH	Mississippi Division of Radiological Health
MED	Medical
MRI	magnetic resonance imaging
NA	not applicable
NCDHHS	North Carolina Department of Health and Human Services
NJDEP	New Jersey Department of Environmental Protection

NMED	Nuclear Material Events Database
NR	not recovered
NRC	Nuclear Regulatory Commission
OTH	Other
PET	positron emission tomography
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
TLD	thermoluminescent dosimeter
TRS	Transportation
VDOT	Virginia Department of Transportation
VORH	Virginia Office of Radiological Health
WDHS	Wisconsin Department of Health Services

## **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 2017 are summarized below. Note that a single event may be listed in more than one event type category.

#### Lost/Abandoned/Stolen Radioactive Sources/Material Events

Seven significant events occurred involving the loss of eight 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)*. Seven Category 2 sources and one Category 3 sources were lost; all of which were subsequently recovered, with the exception of one Category 2 source.

Regarding the seven significant events:

- None of the seven events involved Category 1 sources.
- Six of the seven events involved the loss of Category 2 sources (seven total sources). These were all radiography sources. All but one of the sources were contained within radiography exposure devices.
  - o One of the devices was on a barge that sank in the Bering Sea and was not recovered.
  - Two of the devices were at temporary jobsites; one was left unattended and one fell from a truck moving to the next exposure location. Both of the devices were recovered.
  - Three devices were impounded by law enforcement agencies after arresting members of the radiography crews. All three devices were recovered.
  - o One source was lost and recovered during shipping.
- One of the seven events involved a Category 3 source. This was a brachytherapy source that was lost and recovered during shipping.

#### **Medical Events**

Eleven significant events occurred, all of which were classified as potential Abnormal Occurrences (AOs). Note that these events are considered potential AOs until they complete NRC's formal AO determination process and are reported in NUREG-0090, *Report to Congress on Abnormal Occurrences*:

- Six events involved Y-90 microsphere liver treatments where the administered dose was either greater than prescribed or delivered to an unintended site.
- Two events involved prostate brachytherapy seed implants where the administered dose was either greater than prescribed or delivered to an unintended site.
- One event involved a patient who was administered I-131 for a thyroid scan ordered in error; no activity was prescribed.
- One event involved an error in commercial brachytherapy treatment software that resulted in four patients receiving high dose rate afterloader uterus treatments to unintended sites. It should be noted that one other event that was <u>not</u> classified as a potential Abnormal Occurrence involved similar incorrect treatments to another five patients at a different facility as a result of this software error.
- One event involved a patient who received the intended brachytherapy treatment to the right eye, but the written directive incorrectly specified treatment to the left eye.

In addition to the eleven events above, two other significant events classified as potential Abnormal Occurrences occurred prior to Fiscal Year 2017 and were recently added to NMED.

- One of the events involved a Y-90 microsphere liver treatment where the administered dose was delivered to an unintended site.
- One event involved six patients that received their intended radiopharmaceutical dosages, but their written directives incorrectly specified otherwise.

#### **Radiation Overexposure Events**

Three significant events occurred. Two of the events involved radiographers who received exposures from unshielded radiography sources. In the third event, laboratory personnel received uptakes after a glass ampoule of Am-241 broke.

#### **Release of Licensed Material or Contamination Events**

Three significant events occurred. In one event, a hospital was contaminated after a pediatric patient spit out an I-131 capsule and hid it in his hand. In the other two events, laboratories were contaminated after the integrity of radioactive sources (one sealed source and one glass ampoule) was compromised.

#### Leaking Sealed Source Events

One significant event occurred. In this event, the integrity of a radioactive source was compromised in a laboratory when it was bent to fit into a target holder.

#### **Equipment Events**

Six significant events occurred. Two of the events involved radiography sources that were not returned to their shielded position. Two events involved radioactive sources whose integrity was compromised. Two events involved an error in commercial brachytherapy treatment planning software.

#### **Transportation Events**

Two significant events occurred. Both of the events involved radioactive sources that came out of their lead shielding during shipment because the shielding lids had not been properly secured.

#### **Other Events**

No significant events occurred.

# Nuclear Material Events Database Annual Report: Fiscal Year 2017

## **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 the Idaho National Laboratory (INL) and contains approximately 25,000 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, 2007, and September 30, 2017. The data were downloaded from the NMED on January 12, 2018. 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 <u>http://nmed.inl.gov</u>.

For assistance on searches or other questions, contact Robert Sun (<u>nmednrc@nrc.gov</u>, 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 (FY08-17).

## 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).

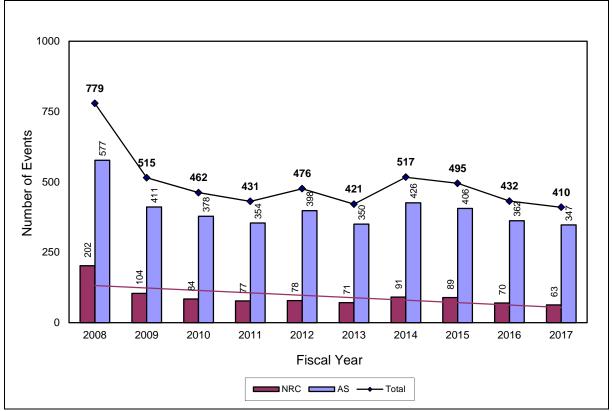


Figure 1. All NMED Events (4,938 total)

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

- In FY17, 379 occurrences accounted for 410 events; a single occurrence can be classified in different event categories.
- The FY08 and FY09 data include 274 and 65 events respectively that resulted from Wal-Mart's onetime review of their tritium exit sign inventory.
- 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.

Event Type	Total	NRC	Agreement State
All NMED Events	-	*	-
Lost/Abandoned/Stolen Material (LAS)	7	-	*
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

#### Table 1. Summary of Trending Analysis

Notes:

- *I* 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 Total and Agreement State-regulated events represent statistically significant decreasing trends (indicated by the trend lines). However, the NRC-regulated events do not represent a statistically significant trend (indicated by the absence of trend line).

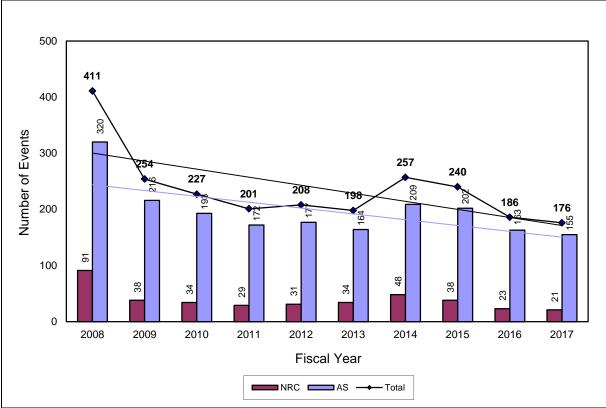


Figure 2. Lost/Abandoned/Stolen Material Events (2,358 total)

The FY08 and 09 data include 143 and 45 LAS events respectively that resulted from Wal-Mart's onetime review of their tritium exit sign inventory.

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 3,887, excluding irretrievable well-logging sources) during the 10-year period and the number that have not been recovered (approximately 2,133), grouped by IAEA category where possible. These included two Category 1 sources, 57 Category 2 sources, and 36 Category 3 sources; all of which were recovered, with the exception of two Category 2 and three Category 3 sources.

					F	iscal Yea	ar					
Cate	gory	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
1	LAS <sup>4</sup>	0	0	0	0	0	0	0	2	0	0	2
•	NR <sup>5</sup>	0	0	0	0	0	0	0	0	0	0	0
2	LAS	11	2	0	2	3	10	5	9	8	7	57
2	NR	0	0	0	1	0	0	0	0	0	1	2
0	LAS	3	1	4	4	7	3	4	4	5	1	36
3	NR	0	0	1	0	1	0	0	1	0	0	3
4	LAS	71	51	76	44	44	24	53	44	41	30	478
4	NR	35	25	26	23	14	9	26	20	17	9	204
L	LAS	129	76	89	82	83	70	88	81	82	48	828
5	NR	57	20	28	11	25	7	33	31	47	12	271
-	LAS	0	2	1	1	0	1	1	2	1	10	19
< 5	NR	0	2	1	0	0	0	0	2	1	1	7
Activity Not	LAS	9	5	13	12	9	7	3	4	2	3	67
Known <sup>1</sup>	NR	0	0	1	0	0	0	0	2	0	0	3
Nuclide		0	0	0	0	0	4	0	4	0	0	
Not	LAS	0	0	0	6	0	1	0	1	0	0	8
Known <sup>2</sup>	NR	0	0	0	5	0	0	0	0	0	0	5
	LAS	460	279	183	209	193	174	330	192	222	150	2392
Other <sup>3</sup>	NR	382	175	127	139	132	92	258	110	159	64	1638
Total	LAS	683	416	366	360	339	290	484	339	361	249	3887
	NR	474	222	184	179	172	108	317	166	224	87	2133

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

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.

Radionuclide	Half-life <sup>1</sup>	Number of Sources Not Recovered <sup>2,3</sup>	Total Activity (Ci)	Total Decayed Activity (Ci) <sup>4</sup>	Total Decayed Activity IAEA Category
lr-192	73.83 days	3	67.0	0.6	4
Pu-238	87.7 years	2	5.3	5.1	3
Total		5	72.3	5.7	3

Table 3. Summary of IAEA Category 1-3 Sources Not Recovered (FY08-17	Table 3. Summar	y of IAEA Ca	tegory 1-3 Sou	rces Not Recover	red (FY08-17
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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 1/12/2018 (data download date).

Radionuclide	Half-life <sup>1</sup>	Number of Sources Not Recovered <sup>2,3</sup>	Total Activity (Ci)	Total Decayed Activity (Ci)⁴	Total Decayed Activity IAEA Category	
lr-192	73.83 days	1	26.3	0.6	4	
Total		1	26.3	0.6	4	

 Table 4. Summary of IAEA Category 1-3 Sources Not Recovered (FY17)

Notes:

- 1. Half-life values from the Chart of the Nuclides, 16<sup>th</sup> 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 1/12/2018 (data download date).

#### 2.2.2 FY17 Data

One hundred seventy-six LAS events occurred in FY17, ten of which involved irretrievable well logging sources. Excluding the irretrievable well logging sources, approximately 249 sources were lost/abandoned/stolen, 87 of which have not been recovered. Of the 249 lost sources, none were Category 1, seven were Category 2, and one was a Category 3 source; all of which were recovered with the exception of one Category 2 source.

Seven of the FY17 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 None

#### Significant Events - Category 2 Source Events

Item Number 160432 - A radiography services company reported that a radiography crew had been arrested in Ardmore, Oklahoma. Their radiography truck, which contained an exposure device and a 1,764.9 GBq (47.7 Ci) Ir-192 source, was impounded by local police at 09:00 on 10/14/2016. The company sent an employee to retrieve the exposure device from the impound lot at about 13:00 on 10/14/2016. The involved individuals' employment was terminated. The incident was discussed at each facility during safety meetings. The company is considering installing cameras in the cabs of all their vehicles.

Item Number 160516 - A radiography services company reported the loss of a radiography exposure device that contained a 973.1 GBq (26.3 Ci) Ir-192 source. The device was lost on 12/7/2016 when the barge it was on sank in the Bering Sea about 12 miles from Dutch Harbor, Alaska, while in transit to Akatun, Alaska. The device was locked in a pelican case with the source in the shielded position. The Coast Guard conducted a detailed search and rescue operation. The pelican case was not observed in the debris field and there is no intent to retrieve the barge.

Item Number 170124 - A radiography services company reported the loss and recovery of a radiography exposure device that contained a 2.22 TBq (60 Ci) Ir-192 source. The company was performing operations under reciprocity in Reeves County, Texas, on 2/20/2017. The radiography crew finished work at one section of pipeline, placed the exposure device on the tailgate of their truck, and drove down the pipeline right-of-way to their next location. The device fell from the truck. A contractor found the device, placed it in the back of his truck, and took it to another radiography crew on the project. The RSO was contacted, who then contacted the responsible radiography crew. The device was surveyed and revealed expected results. The source was in the fully shielded position and the safety plug was in the front of the device. The RSO performed calculations and it did not appear that the contractor received radiation exposure exceeding limits. The Texas Department of State Health Services investigated the incident and determined that the event did not meet reportable requirements as a loss of radioactive material greater than 1,000 times limits under such circumstances that it appears exposure could result to persons in unrestricted areas. Corrective actions included writing a new procedure and providing additional instruction to personnel.

Item Number 170143 - A radiography equipment manufacturer reported that a 3,885 GBq (105 Ci) Ir-192 source was shipped to the wrong location. A radiography services company in Borger, Texas, stated on 3/10/2017 that only one of two sources arrived at their facility. The missing source was contained within a radiography exposure device. The transportation company performed a search and discovered that the source had been shipped to Portland, Oregon. The source was re-routed and arrived at the radiography services company facility on 3/17/2017.

Item Number 170213 - A radiography services company reported the loss and recovery of a radiography exposure device that contained a 3,207.9 GBq (86.7 Ci) Ir-192 source. Radiography was being performed on a liquid natural gas pipeline in Cameron Parish, Louisiana, on 4/20/2017. A pipeline safety officer performed a site visit and observed that the exposure device was left in an unlocked and unattended vehicle. The radiography crew had left to help another crew member working at the site. The crew was not in direct surveillance of the vehicle. The radiography services company's RSO investigated the incident and stated that no radiation exposure to crew members or the general public was possible. Corrective actions included retraining personnel. In addition, transport vehicles at temporary job sites were modified by installing complete alarming systems and transport containers were equipped with automatic locking devices. Each radiographer must install their own locking device when they check out radiography equipment.

Item Number 170439 - A radiography services company reported the theft and recovery of two radiography exposure devices and their associated Ir-192 sources. The sources contained activities of 2,960 and 3,256 GBq (80 and 88 Ci). The company's RSO stated that two radiography crews completed work at field sites near Midland, Texas, on 9/15/2017. The crews decided to terminate their employment and return to the site office in La Porte, Texas. Company management in the Midland office were told of the plan by another radiographer and, with indication from a GPS tracking system, determined that the four radiographers were indeed headed away from the job site and leaving the area. The company contacted the radiographers, told them that they were terminating their employment, and instructed them to take their trucks and radiography devices to the company's facility in Midland, Texas. The radiographers decided to continue to the site office in La Porte. The company reported the theft of the trucks and radiography devices to local law enforcement. Law enforcement pulled both trucks over about an hour out of Midland and placed one of the radiographers in custody for unlawful possession of a vehicle. The other three radiographers were not charged with any crimes. Law enforcement stayed with the trucks until company personnel responded to the site. An investigation by the RSO and the Texas Department of State Health Services determined that the radiographers did not intend to steal the radiography devices, but were going to return to La Porte, Texas, and quit their jobs. Corrective actions included terminating the radiographers' employment.

#### Significant Events - Category 3 Source Events

Item Number 170419 - A medical equipment manufacturer reported the loss and recovery of a 140.3 GBq (3.792 Ci) Ir-192 brachytherapy source. The source had been removed from a high dose rate afterloader unit at a hospital in New York and prepared for shipment to Louisiana for disposal. The packaged source was picked up from the hospital by a common carrier on 8/21/2017. The source arrived at the common carrier's local station in New York on 8/22/2017. However, when the medical equipment manufacturer checked the package's tracking information on 8/30/2017, it indicated that the package was still at the common carrier initiated a station trace on the package. The common carrier located the package on 9/1/2017; it had been delivered to the appropriate location on 8/29/2017.

#### Events of Interest

Item Number 160486 - A hospital reported that a 3.7 MBq (100  $\mu$ Ci) I-125 localization seed was left inside a patient. The seed was implanted in the patient on 11/14/2016 for localization of a non-palpable breast lesion. Tissue was removed on 11/17/2016 and sent to pathology on 11/18/2016. The patient also received a sentinel node procedure that same day and received a dosage of Tc-99m. The hospital believed that the seed had been removed with the tissue sample. However, the seed was not located. A search of hospital was conducted with negative results. Initially, the hospital reported that the seed was lost on 11/21/2016. The patient returned to the hospital on 11/22/2016 for post-operative evaluation. Radiation surveys identified that the seed was still inside the patient. The seed was removed later that day. The Oklahoma Department of Environmental Quality investigated the incident. The calculated dose to tissue at 5 cm surrounding the seed for eight days was 0.832 cGy (rad). The incident cause was determined to be human error. Corrective actions included a change in procedures to locate, identify, contain, and label surgically removed localization seeds.

Item Number 170011 - Law enforcement personnel reported finding radioactivity at the intersection of Route 123 and the I-95 southbound exit ramp near Woodbridge, Virginia, on 12/29/2016. The radioactivity was identified on a grassy knoll in the median of the interchange. The Prince William County Hazardous Material Unit responded and identified Cs-137. Radiation levels were measured at 10 mR/hour at 1.5 feet from the ground and between 30 and 50 mR/hour at ground level. The Virginia Department of Transportation (VDOT) had responsibility for the area and was requested to arrange for mitigation of the source. The Virginia Office of Radiological Health (VORH) also took mitigation action. A radiation consulting firm was contacted and arrived at the site. A Cs-137 source with an activity of about 370 MBq (10 mCi) was found under approximately one inch of soil. The contact exposure rate was 900 mR/hour. The source was approximately 7 mm in diameter and 15 mm long. A leak test of the source and area surveys after removal of the source indicated no radioactive contamination. The source was placed into a lead shield inside a DOT 7A Type A steel drum overpack. It was sent to the consulting firm's facility for temporary storage pending disposition. On 5/2/2017, VDOT notified VORH that the source had been transferred to the source's manufacturer on 1/30/2017 for disposal. On 5/9/2017, VORH determined that the source belonged to a gauge purchased by a construction material testing company in 2006. The gauge was stolen from the company in 2008 (see NMED Item Number 090456).

Item Number 170109 - A plastic packaging manufacturer reported the loss and recovery of a nuclear thickness gauge that contained a 5.55 GBq (150 mCi) Am-241 source (assayed 12/28/2009). The gauge was found in a load of scrap metal at a scrapyard on 2/8/2017. A scrapyard employee measured up to 3 mR/hour using a survey meter. Wisconsin Department of Health Services (WDHS) staff responded to the scrapyard on 2/9/2017. Inspectors determined that the gauge was not leaking, but the shutter was open; they closed the shutter. A licensed service provider transported the gauge back to the plastic packaging manufacturer on 2/10/2017. WDHS performed a reactive inspection at the manufacturer's facility on 2/10/2017. The manufacturer had permanently shut down a product line in January 2017 and contracted demolition of the equipment to a general contractor. The manufacturer did not identify that the gauge was on the product line prior to demolition. At least two contractor employees came in contact with the gauge. WDHS determined that public exposure limits were not exceeded. The manufacturer performed procedure modifications and implemented new training programs to prevent recurrence. This event was classified as an EQP and LAS event.

Item Number 170155 - A radiopharmacy reported that a vehicle fire occurred due to mechanical issues on 3/17/2017 near mile marker 286 on I-76 in Reamstown, Pennsylvania. The vehicle was carrying 79.572718 GBq (2.150614 Ci) of Tc-99m and 40.183739 GBq (1.086047 Ci) of F-18. Pennsylvania Department of Environmental Protection emergency response and radiological health physics staff responded to the scene. The vehicle was entirely engulfed in flames and allowed to burn itself out. The radiopharmacy personnel at the scene collected contaminated debris and ash, which was returned to their facility for decay. The vehicle was then transported to an isolated storage area, allowed to decay to background, and then released on 3/24/2017. The entire area was surveyed and no residual contamination was identified. This event was classified as an EQP, LAS, and TRS event.

Item Number 170319 - A metal recycling company reported finding a Cs-137 source on 6/28/2017 estimated to contain approximately 1.48 GBq (40 mCi). The recycler contacted a radiological services company to identify, wipe test, package, and properly dispose of the source. Radiation levels were 5 R/hour on contact and 2 R/hour at four inches. There was no removable contamination. The source was placed in a shielded container and locked within a sea van container. The exposure rate on contact with the sea van container was less than 1 mR/hr. The New Jersey Department of Environmental Protection (NJDEP) responded to the site on 6/29/2017. NJDEP surveys of the shielded container showed 4 mR/hour on the side and 100 mR/hour on the top with the shielding removed. The source was in the form of a string with an attached metal tag. There were no identifying markings on the string or tag. NJDEP

also observed another container that the recycler stated contained Am-241 industrial smoke detectors and Ra-226 in a sextant and a military-type compass. The radiological services company planned to package the material for disposal in early July.

#### 2.2.3 Events Recently Added to NMED That Occurred Prior to FY17

Thirty-four 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. None 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 None

#### Events of Interest

Item Number 150350 - A steel manufacturer reported that a scrap metal shipment from a metal recycler set off their radiation monitor alarms on 6/5/2015. A radiation survey revealed 500 mR/hour at two meters. Radiation readings in the cab of the truck were 10 mR/hour. The truck's driver had been in the cab for approximately four hours. The load was secured at the steel manufacturer until Florida Bureau of Radiation Control (FBRC) personnel arrived on site. The source was identified as a 0.3 GBq (8 mCi) Cs-137 source attached to a broken source rod from a gauge. Radiation surveys revealed 1.5 R/hour on contact. FBRC determined that the source was from a moisture-density gauge that was stolen in 2008 (see NMED Item Number 080471). The 1.48 GBq (40 mCi) Am-Be source was not recovered. This event was classified as an EQP and LAS event.

Item Number 160213 - A radiopharmacy reported that a courier mistakenly picked up a white pig from a Pennsylvania licensee, which he assumed was empty because it was near other cases that he was returning to the radiopharmacy. As he was loading the pig into his truck on 5/18/2016, the lid opened and two rods fell out onto the ground. He did not realize that they contained radioactive material. The rods were Ge/Ga-68 calibration sources, each containing an activity of 79.92 MBq (2.16 mCi). He placed them in his truck using his hands, leaving the rods unshielded, and returned to the radiopharmacy. He placed the pig and two rods on top of the empty cases in the loading area. The company's RSO found the rods and performed radiation surveys. Results revealed greater than 200 mR/hour on contact and 1.4 mR/hour at one meter. The RSO immediately placed the rods into a shielded pig and began an investigation. Contamination wipes performed on the rods revealed negative results. The RSO stated that there was enough interposed shielding from a large number of other pigs in the courier's vehicle to reduce his radiation exposure to below regulatory limits. The rods were properly packaged and shipped back to the Pennsylvania licensee. The courier's whole body badge was sent for analysis. Dose modeling of the courier's hands was performed. The Pennsylvania Department of Environmental Protection performed a reactive inspection. It was concluded that no radiation overexposure to the driver occurred. The cause of the event was lack of training of the driver. All drivers will be trained to accept/pick-up only properly labeled containers/equipment.

Item Number 170323 - A university reported that an unplanned contamination event occurred as a result of dissolving a 4.63 MBq (125  $\mu$ Ci) Po-210 source, which was part of a static eliminator. Po-210 contamination was discovered when a graduate research assistant was surveying himself upon exiting the laboratory on 12/12/2013. The university's RSO was notified. The laboratory was posted and access was restricted. The contamination caused the restricted area to be closed for more than 24 hours. The

laboratory was subsequently thoroughly decontaminated. The cause of the event was failure to follow procedure or wrong procedure used. Corrective actions included providing new training to personnel. This event was classified as an EQP, LAS, LKS, and RLM event.

## 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).

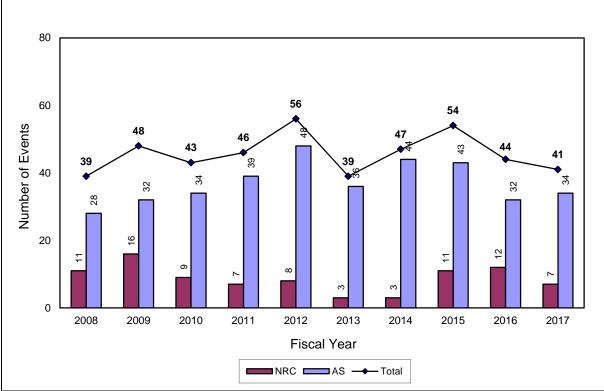


Figure 3. Medical Events (457 total)

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

					Fisca	al Year					
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Medical	12	15	12	14	13	7	11	14	8	11	117
Embryo	2	2	2	1	1	2	1	1	1	0	13
Total	14	17	14	15	14	9	12	15	9	11	130

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 FY17 Data

Forty-one MED events occurred in FY17, 11 of which were considered significant and classified as potential AOs.

#### Significant Events - AOs or Potential AOs

Item Number 170034 - A patient received a dose of Y-90 microspheres on 12/29/2016 that was greater than prescribed. The patient was prescribed an activity of 90.76 MBq (2.453 mCi) to a small lesion on her liver and 816.85 MBq (22.077 mCi) to a large lesion on her liver. Medical staff prepared two vials according to the written directive and labeled each vial shield; they did not label the vials. During the first infusion of microspheres (to the small lesion), the technologist accidentally selected the wrong vial; the contents of the large lesion vial were infused into the small lesion. The technologist identified the error while preparing for the second infusion (to the large lesion). Medical staff decided to infuse the large lesion with the remnants of the first vial (large lesion vial) as well as the contents of the second vial (small lesion vial). To prevent recurrence, the medical facility implemented a requirement to perform a time-out prior to all treatments. The labeling requirements were revised to require that both the vial and vial shield be labeled. The labels will be read three times prior to administration. All pertinent staff received training on the revised protocols in January 2017.

Item Number 170083 - A patient prescribed to receive 6,000 cGy (rad) of Y-90 microspheres to the left lobe of the liver actually received 4,860 cGy (rad) to the left lobe and 3,650 cGy (rad) to the right lobe on 1/31/2017. The patient was known to have challenging anatomy and the only viable treatment location was a narrow window just distal to vasculature that supplies the right lobe of the liver. The interventional radiologist verified the catheter position multiple ways prior to the administration of 1.67 GBq (45 mCi) of Y-90 microspheres. The administration was performed with no apparent complications. However, Bremsstrahlung imaging following the administration showed that microspheres were present in both lobes of the liver. The referring physician and patient were notified of the incident. The licensee believes that the cause was either movement of the catheter from unnoticed patient movement (as subtle as breathing) or angiographically undetected reflux caused by the difference in flow dynamics between the microspheres and both the contrast agent and Tc-99M macro-aggregated albumin used for treatment planning. This event caused no harm to the patient and no change to the patient's medical plans (the right lobe had been treated previously and was already essentially non-functional). A review of the event determined that no change in technique was advised and nothing could have been done differently. The NRC contracted a medical consultant, who concurred with the hospital's analysis.

Item Number 170128 - A patient received a dose of Y-90 microspheres on 2/24/2017 that was 94% greater than prescribed. The prescribed activity was 1.05 GBq (28.37 mCi) but the administered activity was 2.05 GBq (55.35 mCi). The cause was human error at the radiopharmacy when converting the Y-90 activity from GBq to mCi. The patient was informed of the incident on 2/26/2017. The North Carolina Radiation Protection Section performed a reactive inspection on 3/2/2017 and 3/17/2017. Corrective actions included procedure modifications, written directive revisions, and software updates to assist in unit conversions.

Item Number 170134 - A patient only received 27.6 Gy (2,760 rad) to the prostate instead of the prescribed 110 Gy (11,000 rad) during a brachytherapy seed implant on 3/2/2017. The incident involved I-125 seeds with a total activity of 999 MBq (27 mCi). Post CT scans on 3/3/2017 confirmed that the prostate received 74.9% less than prescribed. The medical physicist calculated the dose received by the urethra at 2,602 cGy (rad), the rectum at 861 cGy (rad), and the penile bulb at 8,689 cGy (rad). The physicians do not believe that there will be side effects to the patient's urethra, rectum, or neurovascular

bundle. The cause of the event was human error. Corrective actions taken included providing additional training to personnel and improved supervision.

Item Number 170153 - A patient received 6.838 GBq (184.8 mCi) of Pd-103 to the prostate using 110 brachytherapy seeds on 3/16/2017, instead of the intended 5 GBq (135 mCi) using 80 seeds. The patient was prescribed a dose of 12,500 cGy (rad). However, the administered D90 dose was 157.81% of the prescribed dose. This event was caused by the failure to enter the correct activity per seed into the physics calculations spreadsheet; the spreadsheet contained a value from a previous calculation. An independent verification of the treatment data was not performed. The referring physician and patient were notified of the event. No adverse effect to the patient is expected. Corrective actions included introducing a new secondary hand calculation, revising procedures to require that a blank spreadsheet template be used, and a verbal time-out to verify key parameters prior to treatment.

Item Number 170183 - A patient's I-125 eye plaque treatment was not performed in accordance with the written directive. The eye plaque contained I-125 brachytherapy seeds with a total activity of 1,435.6 MBq (38.8 mCi). The plaque was installed on the patient's right eye on 3/22/2017 and removed on 3/31/2017. The delivered dose was 8,500 cGy (rad). The hospital subsequently determined that although the right eye was the intended treatment site, the written directive prescribed treatment to the patient's left eye. To prevent recurrence, the hospital updated their procedures to verify that the correct eye is indicated on both the treatment plan and the written directive. The Virginia Office of Radiological Health investigated the incident.

Item Number 170217 - A patient received 74 MBq (2 mCi) of I-131 on 4/18/2017 when no activity was prescribed. The patient was prescribed a test for the parathyroid, but received a thyroid scan that was ordered in error by a physician's assistant. The error was discovered during the follow up scan on 4/21/2017. The patient and referring physician were notified of the error. An analysis determined that the dose to the patient's thyroid was 1,630 cGy (rad). The hospital determined that the dosage was ordered through the electronic ordering and records system, without confirmation of the order prior to administration. Additionally, the physician's assistant ordered the dosage orders, and re-training applicable personnel. The hospital suspended I-131 usage until the system was corrected and staff training was completed.

Item Number 170294 - A patient received 54,060 cGy (rad) of Y-90 microspheres to the right lobe of the liver on 6/14/2017, instead of the prescribed 11,000 cGy (rad). This event was caused by using the wrong calibration date (6/11/2017 instead of 6/4/2017) when ordering the microspheres, resulting in a much higher activity. The microsphere vial was surveyed with a dose calibrator prior to administration, but the abnormal results were not questioned. The patient's lung dose from shunting was 2,576 cGy (rad), and 3,449 cGy (rad) cumulative; these values are within the 3,000 cGy (rad) and 5,000 cGy (rad) values, respectively, in the vendor's manual. The prescribing physician discussed the error with the patient. Corrective actions included personnel training and procedure modification to improve step-by-step implementation.

Item Number 170357 - A patient received 1.5 GBq (40.56 mCi) of Y-90 microspheres to a 90 cc liver volume for ablation on 7/28/2017, instead of the prescribed 0.629 GBq (17 mCi). The liver received 80,780 cGy (rad) instead of the prescribed 34,000 cGy (rad). The microspheres were administered to the patient too early, before they decayed to the prescribed activity. The cause was an error by a scheduling nurse who used the pre-treatment plan rather than the final treatment plan. The physicist's pre-treatment calculations and a pre-administration time-out failed to identify the error. The physician was notified and contacted the patient. To prevent recurrence, the spreadsheet used to calculate patient dose was modified to include a check of the administration vial's calibration activity and date versus the prescribed activity and procedure date. The time-out procedure was also modified to confirm the proper activity prior to administration. Applicable personnel were trained on these changes.

Item Number 170399 - A patient received a dose of Y-90 microspheres to the right lobe of the liver on 8/18/2017 that was intended for the left lobe. The patient's treatment plan specified a radioembolization dose of 12,400 cGy (rad) to the left lobe on 8/18/2017, followed by radioembolization of the right lobe approximately one month later. The interventional radiologist and radiation oncologist authorized user signed off on the planning activity for the left lobe via the left hepatic artery on 8/2/2017 and 8/3/2017, respectively. The authorized user completed the written directive to administer 1.74 GBg (47.03 mCi) of Y-90 microspheres. On 8/18/2017, the interventional radiologist placed the catheter in the patient's right hepatic artery, which supplies the right lobe. Medical personnel came to the operating room and a timeout procedure was performed where all parties confirmed the procedure, after which the treatment was administered. An interventional radiologist fellow who assisted in the procedure discovered the error later that day while reviewing the treatment plan. He immediately notified the authorized user, who then notified the RSO. This event was caused by human error due to the interventional radiologist's confusion regarding the intent to treat the right lobe at a later date. The authorized user determined that 1.71 GBq (46.22 mCi) had been administered to the right lobe for an estimated dose of 6,100 cGy (rad). The patient and referring physician were notified of the event. Treatment of the left lobe was rescheduled and no harm to the patient is expected. Corrective actions included modification of the written directive time out procedure and personnel training.

Item Number 170404 - The Mississippi Division of Radiological Health (MDRH) and Georgia Radioactive Materials Program reported that four medical events took place at a hospital between 11/8/2016 and 8/15/2017. The patients had been treated using a high dose rate (HDR) afterloader unit and Ir-192 sources with activities ranging from 192.18 to 327.45 GBq (5.194 to 8.85 Ci). An error in the commercial treatment planning software resulted in an actual source step size of 5 mm instead of the planned 2.5 mm. Each of the patients received less dose than prescribed to the intended treatment site (base of the uterus). In addition, the patients received greater than 50 cSv (rem) and 50% or more to unintended tissue (vaginal canal). Written directives prescribed 2.800 cGy (rad) to three of the patients and 2,700 cGy (rad) to the fourth patient. Each patient was to receive the total dose in four separate fractions to the base of the uterus. All four fractions were affected for one patient, three fractions for two patients, and one fraction for the last patient. The first patient received an estimated dose of 1,844 cGy (rad) to the intended treatment site, which was 65.84% of their prescribed dose. The patient's dose to the unintended site was 2,800 cGy (rad). The second patient received an estimated dose of 2,178 cGy (rad) to the intended treatment site, which was 77.7% of their prescribed dose. The patient's dose to the unintended site was 2,100 cGy (rad). The third patient received an estimated dose of 2,339 cGy (rad) to the intended treatment site, which was 83.55% of their prescribed dose. The patient's dose to the unintended site was 2,100 cGy (rad). The fourth patient received an estimated dose of 2,684 cGy (rad) to the intended treatment site, which was 99.41% of their prescribed dose. The patient's dose to the unintended site was 1,400 cGy (rad). For each patient, the expected dose to the unintended site was between 126 and 175 cGy (rad) per fraction. The referring physician and patients were notified of the incidents. The hospital suspended performing this specific treatment. MDRH conducted a reactive inspection on 9/1/2017. The incidents were discussed with the RSO, medical physicists, and the chair of radiation oncology. NMED Item Numbers 170403 and 170443 are related to this issue. This event was classified as an EQP and MED event.

#### Events of Interest

Item Number 170003 - A patient received a high dose rate brachytherapy treatment to an unintended location on 11/23/2016. The incident involved a high dose rate afterloader unit, an old style 26 mm applicator, a reusable transfer guide tube, and a 299.7 GBq (8.01 Ci) Ir-192 source. The cylinder was placed into the patient by the physician and the marker wire was placed within the tandem. Fluoroscopy was performed to verify that the cylinder applicator was inserted to the proper depth. The physicist then removed the marker wire and inserted the transfer guide tube into the tandem. Patient treatment was completed and the physicist removed the transfer guide tube and cylinder. However, the physicist determined that the inserted length of the transfer guide tube was 7.5 cm shorter than intended.

Consequently, the patient received a single 700 cGy (rad) fraction to an unintended location. The authorized user and patient were notified of the error and the correct fraction was subsequently administered. The hospital's RSO conducted an investigation and interviewed persons involved with the administration. The cause of the incident was identified as a deformed transfer guide tube. The manufacturer confirmed that there was an irregularity in the transfer guide tube and that it was necessary to apply added pressure to fully insert it into the applicator. Corrective actions included removing the transfer guide tube from service and replacing it with a different design, modifying the utilization procedure, counseling staff on the event, and providing training on the new device and procedures. This event was classified as an EQP and MED event.

Item Number 170019 - A patient received a reduced dose to an intended treatment site, and an unintended dose to surrounding healthy tissue during a high dose rate (HDR) brachytherapy procedure on 12/23/2016. A 369.52 GBq (9.987 Ci) Ir-192 source was incorrectly positioned during the third of four HDR fractionated treatments. The treatment was prescribed to a cervical lesion extending primarily on the left lateral side with upper to mid-vaginal involvement. The first two tandem and ovoid HDR treatments were delivered as prescribed on 12/19/2016 and 12/21/2016. However, an incorrect tandem applicator length of 119.8 cm was entered into the treatment planning system during the third fraction on 12/23/2016, instead of the prescribed 131.9 cm. The dose was delivered 12 cm inferior to the intended site. The prescribed dose to the tumor volume was 650 cGy (rad), but the actual dose delivered was 65 cGy (rad) to 90% of the tumor volume. The error was identified prior to the fourth treatment fraction scheduled for 12/29/2016. The patient was informed of the event. The treatment was corrected and then performed on 12/30/2016. The cause was concluded to be human error and a procedure problem. Corrective actions included generating a new procedure and modifying an existing procedure.

#### 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. None of these events occurred in FY17.

#### 2.3.3 Events Recently Added to NMED That Occurred Prior to FY17

Five 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. Two of the MED events were considered significant and classified as potential AOs. 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

Item Number 170074 - A patient received a dose of Y-90 microspheres to the right lobe of the liver on 4/8/2016 that was intended for the left lobe. The hospital planned to treat the patient's liver in two fractions. The first fraction involved treating the right lobe, which was successfully completed on 3/3/2016. The second fraction involved treatment of the left lobe, for which the written directive prescribed 4.15 GBq (112.16 mCi) for a dose of 11,700 cGy (rad). The catheter placement was confirmed by the interventional radiologist with an angiogram. The delivered activity was 4.07 GBq (110 mCi). Following administration of the second fraction, PET/MRI images were taken on 4/8/2016 and read on 4/16/2016. The images indicated that approximately 95% of the microspheres were deposited in the right lobe, with the remainder in the left lobe. The patient was notified of this event on 4/20/2016. The dose to the right lobe during the second fraction was 9,380 cGy (rad). When combined with the first fraction, the cumulative dose to the right lobe was 21,180 cGy (rad). The NRC contracted a medical consultant to review this event, who calculated the cumulative dose to the right lobe to be 21,200 cGy (rad). The hospital thought that the incident was not a medical event due to patient intervention (shifting the catheter tip location by breathing, coughing, or other movement). NRC Headquarters and Region III

determined that the incident was a medical event on 1/30/2017 and requested that the hospital report the event. The patient did not experience any significant changes to liver function that were inconsistent with liver cancer, and had no abdominal pain. The left lobe of the liver was subsequently treated with chemotherapy. The hospital reviewed this event with applicable personnel to identify process improvement opportunities.

Item Number 170236 - A patient prescribed to receive 925 MBq (25 mCi) of Ra-223 dichloride was administered 958 MBq (25.9 mCi) of I-131 on 3/31/2017. The prescribing physician intended that the patient be administered the I-131 dosage, but the written directive incorrectly listed Ra-223. Five other cases were also reported in which written directives did not match the intended dosages, but the patients received their intended dosages. Four of these cases occurred between 12/3/2015 and 8/18/2016 and involved the use of a pre-printed form with the wrong unit selected; the intended dosages were in  $\mu$ Ci, but the written directives specified mCi. The fifth case occurred on 2/23/2016 and involved a transcription error in which the intended dosage was  $121 \mu$ Ci, but the written directive specified  $211 \mu$ Ci. The patients were not notified because they received their intended dosages. No harm to the patients was expected. Corrective actions included updating forms/procedures and personnel training.

#### Events of Interest

Item Number 170443 - Five patients received doses that exceeded reportable limits. The patients had been treated using a high dose rate (HDR) afterloader unit and Ir-192 sources with activities ranging from 355.57 to 440.3 GBq (9.61 to 11.9 Ci). An error in the commercial treatment planning software resulted in an actual source step size of 5 mm instead of the planned 2.5 mm. The hospital became aware of the software error when the software vendor notified them on  $\frac{8}{22}/2017$ . All five patients were treated for malignant neoplasm of cervix uteri. The targeted patient area that received reportable radiation dose was the tissue of the upper vaginal wall in each of the five patient cases. The first patient was prescribed to receive a total dose of 2,720 cGy (rad) during four fractions, but only received 2,054.6 cGy (rad) to the intended treatment site, which was 24.46% less than their prescribed dose. The second patient was prescribed to receive a total dose of 3,000 cGy (rad) during five fractions, but only received 2,370 cGy (rad) to the intended treatment site, which was 21% less than their prescribed dose. The third patient was prescribed to receive a total dose of 2,750 cGy (rad) during five fractions, but only received 1,871 cGy (rad) to the intended treatment site, which was 31.96% less than their prescribed dose. The fourth patient was prescribed to receive a total dose of 2,600 cGy (rad) during four fractions, but only received 1,935 cGy (rad) to the intended treatment site, which was 25.58% less than their prescribed dose. The fifth patient was prescribed to receive a total dose of 2,750 cGy (rad) during four fractions, but only received 2,175.6 cGy (rad) to the intended treatment site, which was 20.89% less than their prescribed dose. There were no doses to unintended treatment sites for any of the patients. The authorized user stated that the treatment site for each patient was considered to be the entire reproductive system (ovaries, cervix, and vagina). While it is true that the treatment planning software error resulted in unintended dose to the lower vagina as the source path extended beyond the planned endpoint within the applicator and in some cases started on a return path back into the lower vagina, that tissue was protected to a degree by the fluid-filled sleeve into which the applicator was inserted. The lower vaginal walls were both shielded by the sleeve and were pushed further away from the source. That complicated the dose estimation to that tissue. The authorized user stated that performing a full analysis of the dose to that tissue would take several weeks and would severely impact therapy schedules. Estimates of the variance of the dose to organs or tissue that were not part of the treatment site were previously made, although that information was not included in the report. The hospital contacted all five patients and their referring physicians. The hospital suspended performing this specific treatment until the software is updated. NMED Item Numbers 170403 and 170404 are related to this issue. This event was classified as an EQP and MED event.

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).

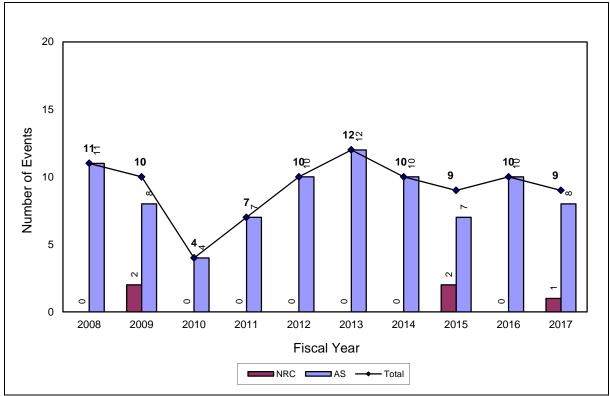


Figure 4. Radiation Overexposure Events (92 total)

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.

	Fiscal Year										
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Immediate	0	0	0	1	1	0	0	0	1	1	4
24-Hour	3	1	1	0	4	1	3	4	1	2	20
30-Day	8	9	3	6	5	11	7	5	8	6	68
Total	11	10	4	7	10	12	10	9	10	9	92

#### Table 6. EXP Events Classified by CFR Reporting Requirement

#### 2.4.2 FY17 Data

Nine EXP events occurred in FY17, three of which were considered significant.

#### Significant Events - Immediate Reporting

Item Number 170398 - A federal laboratory reported the discovery of a broken flame-sealed glass ampoule that contained a well-characterized solution of Am-241 with an activity of 47 MBg (1.27 mCi). The activity was in a solution of nitric acid. The ampoule broke sometime between 6/26/2017 and 8/8/2107; the incident was discovered on 8/18/2017. Contamination was primarily located inside the lead cave where the ampoule was stored, although low-level alpha contamination was identified in other laboratories and office spaces in the building. No contamination was identified outside of the building. Access to the area was restricted. A total of 31 personnel were potentially exposed to the broken ampoule. All 31 individuals submitted urine bioassay samples, with only two (individuals #1 and #2) exceeding the detection limits. The five individuals with the highest risk of exposure (including individual #1) also received lung and whole body counts, which were negative. Based on the urine bioassay, individual #1 was administered chelating agents to reduce internal dose. Individuals #1 and #2 received additional whole and partial body in-vivo counts and provided additional urine bioassay samples to refine their dose estimates and the exposure pathway. Current estimates for individual #1 show a potential TEDE of 25 cSv (rem) or more and at least 87 cSv (rem) to the bone surface. NRC began a special inspection into this event on 9/26/2017. Corrective actions included repackaging similar ampoules, revising procedures, and improving personnel monitoring. This event was classified as an EQP, EXP, and RLM event and a potential Abnormal Occurrence.

#### Significant Events - Within 24-Hour Reporting

Item Number 170221 - A radiography services company reported that a radiographer trainee's selfreading dosimeter went off scale on 4/28/2017 at a temporary jobsite in La Port, Texas. Radiography was being performed using a 1.89 TBg (51 Ci) Ir-192 source. Work was stopped and the individual's optically stimulated luminescence dosimeter was sent for processing. A verbal report from the dosimetry vendor on 4/29/2017 revealed an exposure of 5.392 cSv (rem). An investigation on 6/7/2017 determined that the trainee did receive the 5.392 cSv (rem) dose. The trainee had climbed ropes to position the exposure device 30 feet above the floor in a pipe rack. Following the exposure, the trainee climbed back up to collect the film, but failed to take a survey meter. Therefore, the trainee was unable to detect that the source was not fully shielded. Due to excessive noise, the trainee would not have heard his alarming rate meter. The trainee lowered the film by rope for developing and then stayed near the exposure device. After about 20 minutes, the trainer returned to say that the film was good and the trainee attempted to disconnect the source cable. When it failed to disconnect, another trainer turned the crank handle about half a turn to fully retract the source. The trainee immediately lowered himself to the ground and found that his pocket dosimeter was off scale. The trainer contacted the RSO, who stopped work at the site. The trainee was subsequently released from employment. However, he reported that he experienced no redness or tingling in his hand. The RSO completed a calculation on 6/16/2017, revealing an extremity exposure of 10 cSv (rem) to the trainee's right hand. The company held stand down briefings and

disciplined employees. The root cause was that no post exposure survey was performed to confirm that the source was retracted into the shielded position. As of 6/13/2017, this incident had a final International Nuclear Event Scale rating level of 2. This event was classified as an EQP and EXP event.

Item Number 170272 - A radiography services company reported that a radiographer received 176 cSv (rem) to each hand on 5/15/2017 at paper mill in Wisconsin Rapids, Wisconsin. Radiography was being performed using a 3.55 TBq (96 Ci) Se-75 source with a 17.5 half-value layer collimator. The radiographer was distracted by a radio call from the assistant radiographer and failed to retract the source into the exposure device following a shot. The radiographer approached the collimator (containing the source) without his survey meter and adjusted the position of the collimator. A re-enactment performed the next day revealed that the radiographer held the collimator on two separate occasions, once in each hand, for approximately three to five seconds each. During this time, the radiographer's fingers were in the uncollimated beam. The radiographer stated that his alarming rate meter did not alarm, which is possible due to the radiation profile of Se-75. A direct reading dosimeter worn on the radiographer's chest revealed an exposure of 100 mR. His whole body badge was sent for rush processing and subsequently revealed an exposure of 1.52 mSv (152 mrem). A dose assessment showed that each hand received 176 cSv (rem). The Wisconsin Department of Health Services (WDHS) performed a site investigation on 5/17/2017. The radiography services company monitored the radiographer's hands for at least seven weeks. No changes in skin color were noted. The company determined that the root cause of the event was the radiographer's failure to use a radiation survey meter when approaching the source collimator. Contributing causes included the dosimetric profile of Se-75, distractions associated with digital radiography, and lack of visual contact between the radiographer and assistant radiographer. Corrective actions included providing additional training to personnel. WDHS determined the root cause of the event was the radiographer wrapping his hands around the collimator in a way that exposed his hands to the uncollimated beam. As of 5/24/2017, this incident had a final International Nuclear Event Scale rating level of 2. This event was classified as an EOP and EXP event.

#### Events of Interest

Item Number 170286 - A radiopharmacy reported elevated radiation levels and doses above limits to three non-radiation workers. On 5/10/2017, the radiopharmacy reported that the highest area dosimeter reading for the month of April was 12.276 cSv (rem). There were no neutron readings, which indicated that the elevated readings were likely from the radiopharmaceutical production process rather than the cyclotron. The radiopharmacy was advised to cease operations pending an investigation. Inspectors from the Illinois Emergency Management Agency (IEMA) arrived on 5/11/2017. No immediate issues with the cyclotron or hot cell were identified. However, radiopharmacy engineers believed that the root cause was related to problems in the cyclotron's target and delivery systems, resulting in multiple instances of F-18 escaping from a v-vial vent. Material accumulated in the ventilation ducts leading to filter banks near the area dosimeters. After making numerous inquiries regarding duties and distances to work stations, exposures to three non-radiation workers opposite the adjoining wall were determined to be 1.2 mSy (120 mrem), 1.49 mSv (149 mrem), and 2.62 mSv (262 mrem). Corrective actions included additional maintenance, monitoring of target delivery systems, adding an alarming radiation detector in the cyclotron vault, upgraded shielding, and additional area dosimeters on the opposite side of the adjoining wall. The radiopharmacy is under heightened oversight by IEMA until corrective measures are fully implemented and proven effective. An ongoing investigation found instances of low pressure observed in the past, but they did not result in low yields of F-18 or cyclotron issues; therefore, they were not investigated further. Additional technical issues were discovered, including low saturation yields, drops in cooling water flow rate, an increase in chiller water temperature, and a faulty motor in the cyclotron exhaust fan. IEMA inspectors and NRC representatives believe that the root cause of the event is a combination of factors, including the technical issues above, which resulted in increased volatilization of F-18 and plating out of radioactive material in the ductwork prior to the shielded filters. Additionally, inadequate training of staff and lack of corrective actions, as well as lack of attention to observed production trends, likely contributed to the incident. Subsequent dose calculations indicated that

additional target handling lapses may have contributed to the increased exposures beyond the contribution from F-18 leaks.

Item Number 170446 - A radiopharmacy reported that a cyclotron engineer received an extremity exposure of 79.251 cSv (rem) to his left hand and 94.517 cSv (rem) to his right hand. The engineer worked on multiple components within two separate cyclotrons during the week of 7/17/2017. The exposures were noted on the dosimetry report from his ring badges. His whole body dosimetry result for the entire month of July 2017 was 6.8 mSv (680 mrem). No unusual work was noted for the event week and normal radiation exposures were recorded for all prior weeks. The Pennsylvania Department of Environmental Protection performed a reactive inspection on 8/17/2017. With the type of cyclotron maintenance the engineer performed, there was a potential for contact with several hundred mCi of residual F-18 remaining in the cyclotron systems. Based on the differences in whole body badge results and ring dosimeter results, it is probable that there was undetected radioactive contamination on the gloves, rings, or skin of the engineer's hands. The radiopharmacy believes the cause to be failure to conduct contamination surveys in a timely manner while working with or near F-18. They will develop a training module and disseminate it for mandatory viewing with a test to confirm completion. In addition, they will review their personal protection equipment and make changes if necessary.

#### 2.4.3 Events Recently Added to NMED That Occurred Prior to FY17

Two EXP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Neither 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.

<u>Significant Events - Immediate Reporting</u> None <u>Significant Events - Within 24-Hour Reporting</u> None <u>Events of Interest</u> 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 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 trend line).

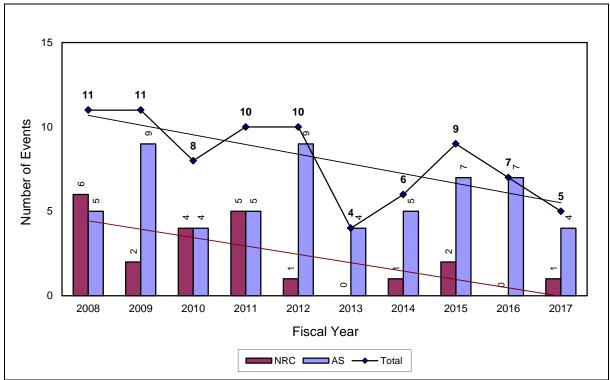


Figure 5. Release of Licensed Material or Contamination Events (81 total)

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.

	Fiscal Year										
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Immediate	2	1	2	0	2	1	1	0	0	3	12
24-Hour	8	6	4	9	6	2	3	9	7	2	56
30-Day	1	4	2	1	2	1	2	0	0	0	13
Total	11	11	8	10	10	4	6	9	7	5	81

Table 7. RLM Events Classified by CFR Reporting Requirement

#### 2.5.2 FY17 Data

Five RLM events occurred in FY17, three of which were considered significant.

#### Significant Events - Immediate Reporting

Item Number 170062 - An unplanned contamination event occurred at a hospital on 1/24/2017. A nominal dose of 1.11 GBg (30 mCi) of I-131 in capsule form was given to a child within the nuclear medicine department. Staff checked on the patient several times and during one visit discovered that the patient had not swallowed the capsule as instructed. The patient instead spit the capsule out into their hand and hid it. That action was considered to be patient intervention and resulted in extensive contamination of the patient's hand, clothing, and the chair the patient was sitting in. The surrounding area was also contaminated. The partially ingested capsule was placed into the radioactive trash upon discovery. During the evaluation and decontamination process, additional contamination was discovered in adjacent camera rooms and corridors where staff had traversed. Initial estimates suggested that the patient ingested little if any of the activity and that excessive levels of contamination were spread throughout the nuclear medicine department. Barriers were erected and the nuclear medicine department was closed for over 48 hours while performing assessment and decontamination. Illinois Emergency Management Agency (IEMA) inspectors were at the site on 1/26/2017 to perform assessment of exposure, contamination levels, potential staff uptake, and corrective actions. Initial bioassay results suggested only negligible staff uptakes occurred. Potential exposures/uptakes continued to be evaluated throughout the decontamination process. IEMA concluded that the technologist involved used reasonable care to ensure that the child swallowed the capsule. A practice run with a placebo prior to the treatment went well. Thyroid counts for radiation workers and general staff revealed uptake results of less than 1 mSv (100 mrem). On 3/2/2017, the nuclear medicine department was back in operation on a reduced scale; two rooms were still closed off for radionuclide decay. Corrective actions included procedure modifications.

Item Number 170118 - A university reported a leaking 111 kBq ( $3 \mu$ Ci) U-235 source (1.5 grams, in powder form) that resulted in radioactive contamination of public areas. A federal laboratory loaned the source to the university for experimentation, research, education, and calibration purposes. The integrity of the source was compromised during an experiment on 2/11/2017 when the corners of the source were bent to fit into a target holder. No leak tests were performed at that time because the source was compromised and leak testing would have presented a radiological hazard. The source was packaged to prevent further contamination and isolated pending disposal. The two involved researchers decontaminated their hands and work surfaces. The RSO was not notified until 2/14/2017. The university Radiation Safety Office was not notified until 2/15/2017. Given the lapse in time between the incident and the time the Radiation Safety Office was notified, standard operating procedures were not followed. The two researchers and one other person identified as being in contact with the source received lung scans on 2/15/2017, which revealed negative results. North Carolina Department of Health and Human Services (NCDHHS) personnel were dispatched to the site on 2/15/2017. The highest reading in proximity to the source revealed 7,000 cpm and 4,280 dpm. Radioactive contamination was

discovered outside anticipated areas on 2/16/2017. Radiation surveys were expanded to bathrooms, stairwells, hallways, and other high traffic areas. Two additional researchers were identified as possibly having contact with the source on 2/11/2017 (for a total of five people) and received lung scans on 2/17/2017, with negative results. Whole body scans were also conducted, with negative results. Surveys and wipes were expanded to the residences of personnel directly involved with the leaking source. One researcher's residence revealed contamination on a toilet seat, which was decontaminated (other surveys and wipes of the residence revealed negative results). A keyboard in that researcher's office was also found contaminated and removed for isolation. The university expanded personnel testing to included urinalysis and blood work, as advised by the Radiation Emergency Assistance Center/Training Site (REAC/TS). It is believed that the contamination was contained and no members of the public received radiation exposure. Immediate corrective actions including shutting down the affected operations pending procedure modification and personnel training, which were completed by 3/27/2017. The involved laboratory manager was demoted and replaced. The university is considering hiring a consultant to help with procedural improvements and restoring safety culture. The university also committed to leak testing all sealed sources, face-to-face training of new researchers, and upgrading radiological analyses equipment and facilities. NCDHHS concluded their investigation and considered the incident an unplanned contamination event. This event was classified as an EQP, LKS, and RLM event.

Item Number 170398 - A federal laboratory reported the discovery of a broken flame-sealed glass ampoule that contained a well-characterized solution of Am-241 with an activity of 47 MBq (1.27 mCi). The activity was in a solution of nitric acid. The ampoule broke sometime between 6/26/2017 and 8/8/2107; the incident was discovered on 8/18/2017. Contamination was primarily located inside the lead cave where the ampoule was stored, although low-level alpha contamination was identified in other laboratories and office spaces in the building. No contamination was identified outside of the building. Access to the area was restricted. A total of 31 personnel were potentially exposed to the broken ampoule. All 31 individuals submitted urine bioassay samples, with only two (individuals #1 and #2) exceeding the detection limits. The five individuals with the highest risk of exposure (including individual #1) also received lung and whole body counts, which were negative. Based on the urine bioassay, individual #1 was administered chelating agents to reduce internal dose. Individuals #1 and #2 received additional whole and partial body in-vivo counts and provided additional urine bioassay samples to refine their dose estimates and the exposure pathway. Current estimates for individual #1 show a potential TEDE of 25 cSv (rem) or more and at least 87 cSv (rem) to the bone surface. NRC began a special inspection into this event on 9/26/2017. Corrective actions included repackaging similar ampoules, revising procedures, and improving personnel monitoring. This event was classified as an EOP. EXP. and RLM event and a potential Abnormal Occurrence.

#### Events of Interest None

# 2.5.3 Events Recently Added to NMED That Occurred Prior to FY17

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. Neither 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 - Immediate Reporting None

### Events of Interest

Item Number 160412 - A radiologically contaminated material recycling company reported an unplanned contamination event that occurred on 9/29/2016. While emptying a 55-gallon drum of lead for reuse, unknown and unsuspected contamination levels in the bottom of the drum resulted in contamination of

the area to a maximum level of 2,000,000 dpm/100 cm<sup>2</sup> beta. Contamination levels in the drum were also determined to be 2,000,000 dpm/100 cm<sup>2</sup> maximum post event. Pre-job surveys identified no elevated contamination levels in the top of the drum. Three personnel received skin contamination and were decontaminated. The area was decontaminated, but not within 24 hours. It was estimated that an activity of approximately 37 MBq (1 mCi) of Sr-90 was involved. Five workers received urine bioassays and results revealed 1.44, 2.89, 18.28, 52.54, and 66.6 Bq/liter (39, 78.2, 494, 1420, and 1800 pCi/liter). Corrective actions involved procedure modifications to include treating the area as a fixed contamination area, opening any unknown container in a HEPA-filtered space, and performing more thorough radiation surveys prior to sorting container contents. In addition, a training session was held on 10/26/2016 for all crew to cover lessons learned and incident debrief.

Item Number 170323 - A university reported that an unplanned contamination event occurred as a result of dissolving a 4.63 MBq (125  $\mu$ Ci) Po-210 source, which was part of a static eliminator. Po-210 contamination was discovered when a graduate research assistant was surveying himself upon exiting the laboratory on 12/12/2013. The university's RSO was notified. The laboratory was posted and access was restricted. The contamination caused the restricted area to be closed for more than 24 hours. The laboratory was subsequently thoroughly decontaminated. The cause of the event was failure to follow procedure or wrong procedure used. Corrective actions included providing new training to personnel. This event was classified as an EQP, LAS, LKS, and RLM event.

# 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).

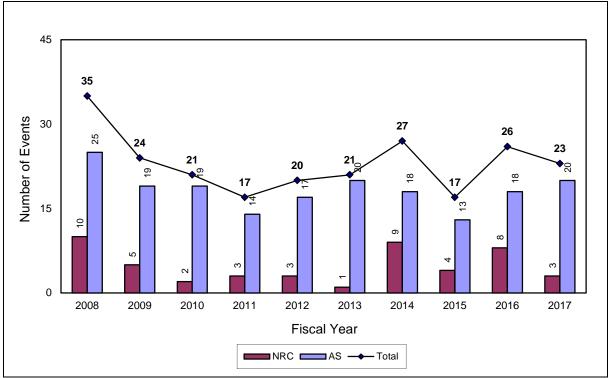


Figure 6. Leaking Sealed Source Events (231 total)

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 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 FY17 Data

Twenty-three LKS events occurred in FY17, one of which was considered significant.

### Significant Events

Item Number 170118 - A university reported a leaking 111 kBq (3  $\mu$ Ci) U-235 source (1.5 grams, in powder form) that resulted in radioactive contamination of public areas. A federal laboratory loaned the source to the university for experimentation, research, education, and calibration purposes. The integrity of the source was compromised during an experiment on 2/11/2017 when the corners of the source were bent to fit into a target holder. No leak tests were performed at that time because the source was compromised and leak testing would have presented a radiological hazard. The source was packaged to prevent further contamination and isolated pending disposal. The two involved researchers decontaminated their hands and work surfaces. The RSO was not notified until 2/14/2017. The university Radiation Safety Office was not notified until 2/15/2017. Given the lapse in time between the

incident and the time the Radiation Safety Office was notified, standard operating procedures were not followed. The two researchers and one other person identified as being in contact with the source received lung scans on 2/15/2017, which revealed negative results. North Carolina Department of Health and Human Services (NCDHHS) personnel were dispatched to the site on 2/15/2017. The highest reading in proximity to the source revealed 7,000 cpm and 4,280 dpm. Radioactive contamination was discovered outside anticipated areas on 2/16/2017. Radiation surveys were expanded to bathrooms, stairwells, hallways, and other high traffic areas. Two additional researchers were identified as possibly having contact with the source on 2/11/2017 (for a total of five people) and received lung scans on 2/17/2017, with negative results. Whole body scans were also conducted, with negative results. Surveys and wipes were expanded to the residences of personnel directly involved with the leaking source. One researcher's residence revealed contamination on a toilet seat, which was decontaminated (other surveys and wipes of the residence revealed negative results). A keyboard in that researcher's office was also found contaminated and removed for isolation. The university expanded personnel testing to included urinalysis and blood work, as advised by the Radiation Emergency Assistance Center/Training Site (REAC/TS). It is believed that the contamination was contained and no members of the public received radiation exposure. Immediate corrective actions including shutting down the affected operations pending procedure modification and personnel training, which were completed by 3/27/2017. The involved laboratory manager was demoted and replaced. The university is considering hiring a consultant to help with procedural improvements and restoring safety culture. The university also committed to leak testing all sealed sources, face-to-face training of new researchers, and upgrading radiological analyses equipment and facilities. NCDHHS concluded their investigation and considered the incident an unplanned contamination event. This event was classified as an EQP, LKS, and RLM event.

#### Events of Interest

Item Number 170435 - A hospital reported a leaking brachytherapy flexible film conformal source that contained 185 MBq (5 mCi) of P-32. The source was used to treat a patient's tumor on the lateral surface of the left eye. Prior to patient treatment on 8/24/2017, the source was wipe tested with no removable contamination detected. At the completion of treatment, the source was removed from the patient and placed into a water bath for shielding. Radiation safety personnel surveyed the patient's treatment area and identified 10,000 cpm or approximately 1,184 Bq (32 nCi). Towels, bowls, water, and other material used during the patient procedure were also radioactively contaminated. Initial investigation revealed no visible damage to the source. The source was transferred to radiation safety and is being held in storage for further investigation. The hospital stated that the patient received their prescribed dose and the physicians do not anticipate any harm to the patient. The hospital will simulate the procedure using a test sample to determine where the leakage and contamination might have occurred. The hospital suspended further treatments with P-32 eye plaques until patient safety concerns have been addressed. This event was classified as an EQP and LKS event.

#### 2.6.3 Events Recently Added to NMED That Occurred Prior to FY17

Four LKS 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 170323 - A university reported that an unplanned contamination event occurred as a result of dissolving a 4.63 MBq (125  $\mu$ Ci) Po-210 source, which was part of a static eliminator. Po-210 contamination was discovered when a graduate research assistant was surveying himself upon exiting the laboratory on 12/12/2013. The university's RSO was notified. The laboratory was posted and access was

restricted. The contamination caused the restricted area to be closed for more than 24 hours. The laboratory was subsequently thoroughly decontaminated. The cause of the event was failure to follow procedure or wrong procedure used. Corrective actions included providing new training to personnel. This event was classified as an EQP, LAS, LKS, and RLM event.

# 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).

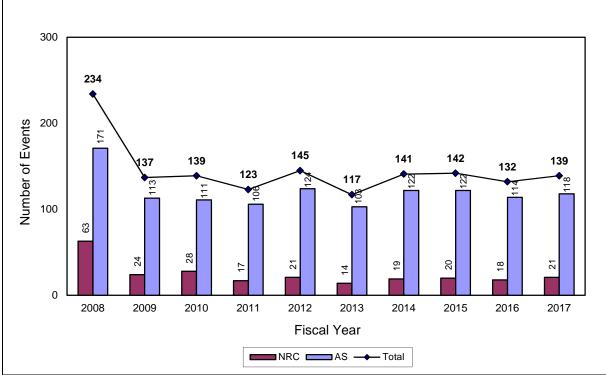


Figure 7. Equipment Events (1,449 total)

The FY08 and 09 data include 131 and 20 EQP events, respectively, which resulted from Wal-Mart's one-time review of their tritium exit sign inventory.

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 FY17 Data

One hundred thirty-nine EQP events occurred in FY17, six of which were considered significant.

### Significant Events

Item Number 170118 - A university reported a leaking 111 kBq (3  $\mu$ Ci) U-235 source (1.5 grams, in powder form) that resulted in radioactive contamination of public areas. A federal laboratory loaned the source to the university for experimentation, research, education, and calibration purposes. The integrity of the source was compromised during an experiment on 2/11/2017 when the corners of the source were bent to fit into a target holder. No leak tests were performed at that time because the source was compromised and leak testing would have presented a radiological hazard. The source was packaged to prevent further contamination and isolated pending disposal. The two involved researchers

decontaminated their hands and work surfaces. The RSO was not notified until 2/14/2017. The university Radiation Safety Office was not notified until 2/15/2017. Given the lapse in time between the incident and the time the Radiation Safety Office was notified, standard operating procedures were not followed. The two researchers and one other person identified as being in contact with the source received lung scans on 2/15/2017, which revealed negative results. North Carolina Department of Health and Human Services (NCDHHS) personnel were dispatched to the site on 2/15/2017. The highest reading in proximity to the source revealed 7,000 cpm and 4,280 dpm. Radioactive contamination was discovered outside anticipated areas on 2/16/2017. Radiation surveys were expanded to bathrooms, stairwells, hallways, and other high traffic areas. Two additional researchers were identified as possibly having contact with the source on 2/11/2017 (for a total of five people) and received lung scans on 2/17/2017, with negative results. Whole body scans were also conducted, with negative results. Surveys and wipes were expanded to the residences of personnel directly involved with the leaking source. One researcher's residence revealed contamination on a toilet seat, which was decontaminated (other surveys and wipes of the residence revealed negative results). A keyboard in that researcher's office was also found contaminated and removed for isolation. The university expanded personnel testing to included urinalysis and blood work, as advised by the Radiation Emergency Assistance Center/Training Site (REAC/TS). It is believed that the contamination was contained and no members of the public received radiation exposure. Immediate corrective actions including shutting down the affected operations pending procedure modification and personnel training, which were completed by 3/27/2017. The involved laboratory manager was demoted and replaced. The university is considering hiring a consultant to help with procedural improvements and restoring safety culture. The university also committed to leak testing all sealed sources, face-to-face training of new researchers, and upgrading radiological analyses equipment and facilities. NCDHHS concluded their investigation and considered the incident an unplanned contamination event. This event was classified as an EOP, LKS, and RLM event.

Item Number 170221 - A radiography services company reported that a radiographer trainee's selfreading dosimeter went off scale on 4/28/2017 at a temporary jobsite in La Port, Texas. Radiography was being performed using a 1.89 TBg (51 Ci) Ir-192 source. Work was stopped and the individual's optically stimulated luminescence dosimeter was sent for processing. A verbal report from the dosimetry vendor on 4/29/2017 revealed an exposure of 5.392 cSv (rem). An investigation on 6/7/2017 determined that the trainee did receive the 5.392 cSv (rem) dose. The trainee had climbed ropes to position the exposure device 30 feet above the floor in a pipe rack. Following the exposure, the trainee climbed back up to collect the film, but failed to take a survey meter. Therefore, the trainee was unable to detect that the source was not fully shielded. Due to excessive noise, the trainee would not have heard his alarming rate meter. The trainee lowered the film by rope for developing and then stayed near the exposure device. After about 20 minutes, the trainer returned to say that the film was good and the trainee attempted to disconnect the source cable. When it failed to disconnect, another trainer turned the crank handle about half a turn to fully retract the source. The trainee immediately lowered himself to the ground and found that his pocket dosimeter was off scale. The trainer contacted the RSO, who stopped work at the site. The trainee was subsequently released from employment. However, he reported that he experienced no redness or tingling in his hand. The RSO completed a calculation on 6/16/2017, revealing an extremity exposure of 10 cSv (rem) to the trainee's right hand. The company held stand down briefings and disciplined employees. The root cause was that no post exposure survey was performed to confirm that the source was retracted into the shielded position. As of 6/13/2017, this incident had a final International Nuclear Event Scale rating level of 2. This event was classified as an EQP and EXP event.

Item Number 170272 - A radiography services company reported that a radiographer received 176 cSv (rem) to each hand on 5/15/2017 at paper mill in Wisconsin Rapids, Wisconsin. Radiography was being performed using a 3.55 TBq (96 Ci) Se-75 source with a 17.5 half-value layer collimator. The radiographer was distracted by a radio call from the assistant radiographer and failed to retract the source into the exposure device following a shot. The radiographer approached the collimator (containing the source) without his survey meter and adjusted the position of the collimator. A re-enactment performed

the next day revealed that the radiographer held the collimator on two separate occasions, once in each hand, for approximately three to five seconds each. During this time, the radiographer's fingers were in the uncollimated beam. The radiographer stated that his alarming rate meter did not alarm, which is possible due to the radiation profile of Se-75. A direct reading dosimeter worn on the radiographer's chest revealed an exposure of 100 mR. His whole body badge was sent for rush processing and subsequently revealed an exposure of 1.52 mSv (152 mrem). A dose assessment showed that each hand received 176 cSv (rem). The Wisconsin Department of Health Services (WDHS) performed a site investigation on 5/17/2017. The radiography services company monitored the radiographer's hands for at least seven weeks. No changes in skin color were noted. The company determined that the root cause of the event was the radiographer's failure to use a radiation survey meter when approaching the source collimator. Contributing causes included the dosimetric profile of Se-75, distractions associated with digital radiography, and lack of visual contact between the radiographer and assistant radiographer. Corrective actions included providing additional training to personnel. WDHS determined the root cause of the event was the radiographer wrapping his hands around the collimator in a way that exposed his hands to the uncollimated beam. As of 5/24/2017, this incident had a final International Nuclear Event Scale rating level of 2. This event was classified as an EQP and EXP event.

Item Number 170398 - A federal laboratory reported the discovery of a broken flame-sealed glass ampoule that contained a well-characterized solution of Am-241 with an activity of 47 MBg (1.27 mCi). The activity was in a solution of nitric acid. The ampoule broke sometime between 6/26/2017 and 8/8/2107; the incident was discovered on 8/18/2017. Contamination was primarily located inside the lead cave where the ampoule was stored, although low-level alpha contamination was identified in other laboratories and office spaces in the building. No contamination was identified outside of the building. Access to the area was restricted. A total of 31 personnel were potentially exposed to the broken ampoule. All 31 individuals submitted urine bioassay samples, with only two (individuals #1 and #2) exceeding the detection limits. The five individuals with the highest risk of exposure (including individual #1) also received lung and whole body counts, which were negative. Based on the urine bioassay, individual #1 was administered chelating agents to reduce internal dose. Individuals #1 and #2 received additional whole and partial body in-vivo counts and provided additional urine bioassay samples to refine their dose estimates and the exposure pathway. Current estimates for individual #1 show a potential TEDE of 25 cSv (rem) or more and at least 87 cSv (rem) to the bone surface. NRC began a special inspection into this event on 9/26/2017. Corrective actions included repackaging similar ampoules, revising procedures, and improving personnel monitoring. This event was classified as an EQP, EXP, and RLM event and a potential Abnormal Occurrence.

Item Number 170403 - A vendor of commercial brachytherapy treatment planning software reported a 10 CFR 21 software issue involving incorrect brachytherapy source step sizes using a high dose rate afterloader. A user in France notified the vendor on 7/13/2017 that they discovered the issue during a quality assurance audit of the software. The measured source paths for certain applicator models have a 2.5 mm source step size. If such an applicator model is used to create a treatment plan while the default step size of the afterloader is 5.0 mm, the actual step size will be incorrect. They will be shown as 2.5 mm steps in the software's 3D view of the applicator, but 5.0 mm in the treatment plan printout. If the error is not caught during treatment plan approval and the plan is exported to the afterloader, the treatment will be performed in 5.0 mm steps. The vendor issued a Field Safety Notification worldwide. The error will be resolved in the next version of the software. NMED Item Numbers 170404 and 170443 are related to this issue.

Item Number 170404 - The Mississippi Division of Radiological Health (MDRH) and Georgia Radioactive Materials Program reported that four medical events took place at a hospital between 11/8/2016 and 8/15/2017. The patients had been treated using a high dose rate (HDR) afterloader unit and Ir-192 sources with activities ranging from 192.18 to 327.45 GBq (5.194 to 8.85 Ci). An error in the commercial treatment planning software resulted in an actual source step size of 5 mm instead of the planned 2.5 mm. Each of the patients received less dose than prescribed to the intended treatment site (base of the uterus). In addition, the patients received greater than 50 cSv (rem) and 50% or more to unintended tissue (vaginal canal). Written directives prescribed 2,800 cGy (rad) to three of the patients and 2,700 cGy (rad) to the fourth patient. Each patient was to receive the total dose in four separate fractions to the base of the uterus. All four fractions were affected for one patient, three fractions for two patients, and one fraction for the last patient. The first patient received an estimated dose of 1,844 cGy (rad) to the intended treatment site, which was 65.84% of their prescribed dose. The patient's dose to the unintended site was 2,800 cGy (rad). The second patient received an estimated dose of 2,178 cGy (rad) to the intended treatment site, which was 77.7% of their prescribed dose. The patient's dose to the unintended site was 2,100 cGy (rad). The third patient received an estimated dose of 2,339 cGy (rad) to the intended treatment site, which was 83.55% of their prescribed dose. The patient's dose to the unintended site was 2,100 cGy (rad). The fourth patient received an estimated dose of 2,684 cGy (rad) to the intended treatment site, which was 99.41% of their prescribed dose. The patient's dose to the unintended site was 1.400 cGv (rad). For each patient, the expected dose to the unintended site was between 126 and 175 cGy (rad) per fraction. The referring physician and patients were notified of the incidents. The hospital suspended performing this specific treatment. MDRH conducted a reactive inspection on 9/1/2017. The incidents were discussed with the RSO, medical physicists, and the chair of radiation oncology. NMED Item Numbers 170403 and 170443 are related to this issue. This event was classified as an EQP and MED event and a potential Abnormal Occurrence.

#### **Events of Interest**

Item Number 160413 - A radiography services company reported a potential radiation overexposure to a radiographer that occurred at their permanent radiographic facility on 10/4/2016. After performing a proper radiation survey, the radiographer moved the exposure device containing a 3.72 TBq (100.6 Ci) Ir-192 source for the next exposure. The radiographer then noticed that the rear fitting had come loose from the control assembly, which showed approximately three inches of drive cable exposed. The radiographer pushed the fitting forward and tightened it back onto the connector of the crank-out control. The company believes that at this point, the source was inadvertently pushed out of the front of the exposure device about three to four inches. The radiographer did not notice this at the time and continued setting up for the next exposure. Upon exiting the cell, the radiographer observed that the red revolving warning light and audible cell alarm had actuated. The radiographer stated that he was inside the cell for five to seven minutes. The radiographer's self-reading pocket dosimeter was off scale. The radiographer immediately notified his RSO, who sent his dosimeter for rushed processing. The RSO estimated the radiographer's whole body exposure at between 5 and 25 R. The radiographer was sent to a local medical laboratory for blood work. The company was advised to contact REAC/TS for guidance. A re-enactment showed that the source did not become inadvertently exposed until after the film was positioned and the collimator was secured. Also, the device nipple was facing away from the radiographer's body. The radiographer's dosimetry results revealed a dose of 1.54 mSv (154 mrem). This event was caused by human error. Corrective actions included switching from aftermarket crank-out controls to the manufacturer's crank-out controls, holding "lessons learned" meetings, and additional annual and refresher training for all technicians.

Item Number 160462 - A radiography services company reported a possible overexposure to a radiographer who failed to fully retract a 1,332 GBq (36 Ci) Ir-192 source into a radiography exposure device on 11/2/2016. Two radiographers were working at a temporary job site at a power plant near Franklin, Texas. After cranking in the source, both radiographers walked to the weld to discuss the next exposure device position. They were about five feet from the device and behind the device, which was partially shielded by conduit and piping. One radiographer walked to the device and, using the quick disconnect, disconnected the guide tube. He noted that the source was protruding from the device about six inches. Both radiographers ran to the crank and cranked in the source, which took about one and a half turns. The radiographers could not hear their alarming rate meters due to excessive noise. Their pocket dosimeters were checked outside the area and were off scale. The RSO was contacted, stopped all

work, requested that the radiographers return to the shop, and checked the exposure device for defects. The radiographers' dosimetry badges were sent for processing. The RSO calculated that the exposure to the hand of the radiographer that disconnected the guide tube was 15.93 cSv (rem). Dosimetry badge results revealed 3.17 and 3.09 mSv (317 and 309 mrem). Annual exposure for both radiographers was 2.761 and 2.053 cSv (rem). The Texas Department of State Health Services performed a reenactment investigation. They calculated that the exposure to the radiographer's hand was 29 cSv (rem); the radiographer's hand passed directly over the source when he pulled the guide tube over the source. The cause of the incident was not retracting the source completely into the exposure device and not using a survey meter to ensure that the source was shielded. Corrective actions included a company meeting/training with employees stressing the importance of safety, following procedures, and being aware of surroundings. The Texas Department of State Health Services retracted this event based on the fact that the cause of the incident was human error and not a broken piece of equipment.

Item Number 160482 - A radiography services company reported that a 2,442 GBq (66 Ci) Ir-192 source disconnected from a radiography exposure device during operations on 11/19/2016. Radiography was being performed at a temporary job site near Mentone, Texas. Following the third exposure, a radiographer retracted the source and went to the device to disconnect the guide tube. After disconnection, the source collimator was pulled to the top of the pipe being inspected and the radiographer's alarming rate meter sounded. His radiation survey meter also went off-scale. He left the area, established a 2 mR/hour boundary, and contacted the RSO. The RSO, who is authorized to recover sources, responded to the site and recovered the source. The control cable was found to be broken approximately one inch from the connector. The company suspected that the automatic lock mechanism malfunctioned. The device and control assembly were sent to the manufacturer for evaluation and repair. The two radiographers received 10 and 80 mR on their pocket dosimeters. The RSO's dosimeters received 131 mR to the chest, with 163 mR to the right hand and 167 mR to the left. Dosimetry badges were sent for emergency processing. No individual received an exposure that exceeded a limit. The manufacturer stated that the failure of the drive cable was due to poor maintenance. The cable had become brittle and packed with dirt. The Texas Department of State Health Services performed an investigation on 1/11/2017. Corrective actions taken by the company included improved supervision for personnel, additional training to personnel, temporarily suspending personnel's qualifications, and inspecting all similar equipment in their inventory.

Item Number 160502 - The Arizona Radiation Regulatory Agency (ARRA) discovered that a construction materials testing company's moisture/density gauge was found in storage with the shutter stuck open. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source. The incident was discovered during a routine unannounced ARRA inspection performed on 11/29/2016. The company sent the gauge to a repair facility. The gauge was repaired and placed back into service. The company informed gauge users to be more aware of gauge condition before and after daily use. A thorough check will also be performed on each gauge during the six-month inventory.

Item Number 170002 - A radiography services company reported that a fire occurred on 12/20/2016 that caused extensive damage to a building containing 12 radiography exposure devices and sources. Ten of the devices contained Ir-192 sources with activities between 1,191.4 and 3,548.3 GBq (32.2 and 95.9 Ci). After the fire was out, exposure rates five feet from the storage location were normal. The company noted that at least two device handles had melted to some degree. The devices were removed from the storage location and radiation surveys were completed. Exposure rates were normal and it appeared that shielding integrity was maintained. No radioactive contamination was identified in the device storage area. The State Fire Marshal determined that the fire was caused by an electrical short at a plug. The corporate RSO returned the devices to the manufacturer for inspection and leak testing. The manufacturer determined that, due to the heat the devices were exposed to, none of the devices could be used to perform radiography work and the Type B containers could not be used for the transportation of

radioactive material. All of the devices will be disposed of by the manufacturer. The manufacturer stated that the sources were leak tested and the devices checked for depleted uranium; results were satisfactory.

Item Number 170003 - A patient received a high dose rate brachytherapy treatment to an unintended location on 11/23/2016. The incident involved a high dose rate afterloader unit, an old style 26 mm applicator, a reusable transfer guide tube, and a 299.7 GBq (8.01 Ci) Ir-192 source. The cylinder was placed into the patient by the physician and the marker wire was placed within the tandem. Fluoroscopy was performed to verify that the cylinder applicator was inserted to the proper depth. The physicist then removed the marker wire and inserted the transfer guide tube into the tandem. Patient treatment was completed and the physicist removed the transfer guide tube and cylinder. However, the physicist determined that the inserted length of the transfer guide tube was 7.5 cm shorter than intended. Consequently, the patient received a single 700 cGy (rad) fraction to an unintended location. The authorized user and patient were notified of the error and the correct fraction was subsequently administered. The hospital's RSO conducted an investigation and interviewed persons involved with the administration. The cause of the incident was identified as a deformed transfer guide tube. The manufacturer confirmed that there was an irregularity in the transfer guide tube and that it was necessary to apply added pressure to fully insert it into the applicator. Corrective actions included removing the transfer guide tube from service and replacing it with a different design, modifying the utilization procedure, counseling staff on the event, and providing training on the new device and procedures. This event was classified as an EQP and MED event.

Item Number 170004 - A coal-fired power plant reported that a nuclear level gauge source holder had fallen from its mounted location. The incident was identified on 12/20/2016. The source holder contained a 740 MBq (20 mCi) Cs-137 source. The source holder fell approximately eight feet onto a checker plate floor. The shutter mechanism and shutter separated from the source holder. Radiation surveys revealed a maximum of 350  $\mu$ Sv/hour (35 mrem/hour) at one foot in the beam path. Radiation surveys at a 20-foot boundary, where danger tape had been placed around the source holder, revealed between 0.1 and 1.2  $\mu$ Sv/hour (0.01 and 0.12 mrem/hour). A technician from the gauge manufacturer arrived at the plant on 12/21/2016. The technician found that the four screws that secure the shutter had sheared off. A new source holder shutter was installed. The source holder was then placed in secure storage onsite pending repair of the source holder mounting bracket, after which the source holder was reinstalled. This event was caused by repairs to a pneumatic ash hopper vibrator several months prior. The vibrator had been reinstalled about 18 inches from the source holder, rather than the typical four to five feet away. Over the next few months, the increased vibration experienced by the source holder caused the failure of the four bolts that secure it to its mounting bracket.

Item Number 170109 - A plastic packaging manufacturer reported the loss and recovery of a nuclear thickness gauge that contained a 5.55 GBq (150 mCi) Am-241 source (assayed 12/28/2009). The gauge was found in a load of scrap metal at a scrapyard on 2/8/2017. A scrapyard employee measured up to 3 mR/hour using a survey meter. Wisconsin Department of Health Services (WDHS) staff responded to the scrapyard on 2/9/2017. Inspectors determined that the gauge was not leaking, but the shutter was open; they closed the shutter. A licensed service provider transported the gauge back to the plastic packaging manufacturer on 2/10/2017. WDHS performed a reactive inspection at the manufacturer's facility on 2/10/2017. The manufacturer had permanently shut down a product line in January 2017 and contracted demolition of the equipment to a general contractor. The manufacturer did not identify that the gauge was on the product line prior to demolition. At least two contractor employees came in contact with the gauge. WDHS determined that public exposure limits were not exceeded. The manufacturer performed procedure modifications and implemented new training programs to prevent recurrence. This event was classified as an EQP and LAS event.

Item Number 170127 - An agricultural crop science company reported that the source shutter on a fixed gauge, which contained a 370 MBq (10 mCi) Cs-137 source, was stuck in the open position. Personnel were in the process of removing the device from the installed position on 2/27/2017 and believed that the

shutter was closed. However, unexpected radiation levels were identified on the survey meter during removal of the device. The device was placed on the room floor with the shutter pointing down. After covering the device with additional lead shielding, it was moved to a storage location. The manufacturer was contacted regarding disposal of the device. A similar gauge with a 370 MBq (10 mCi) Cs-137 source was installed to continue operations. This event did not result in exposure to personnel.

Item Number 170132 - A radiography services company reported that a 3.13 TBq (84.6 Ci) Ir-192 radiography source failed to lock in the shielded position after it was retracted on 3/6/2017. After completing an exposure in arctic conditions at a remote site in the Alpine oil field in Alaska, the radiographer retracted the source and surveyed the exposure device prior to moving it to the next weld. The radiographer did not recognize that the source did not auto-lock in the shielded position. Upon setting the exposure device down, the radiographer's dose rate meter alarmed, his survey meter was off scale, and his pocket dosimeter was off scale. The radiographer then retracted the source a quarter turn back into the shielded position and verified that the auto-lock engaged. The company believes that the source moved from the fully shielded position while the radiographer carried the exposure device between welds. The night foreman immediately suspended radiographic operations and removed the radiographer and the assistant radiographer from the job site. Preliminary calculations resulted in an estimated whole body dose to the radiographer of between 3.5 and 39 cSv (rem). Although it did not appear that the assistant radiographer received any excess radiation exposure, the dosimeters for both individuals were sent for emergency processing. The dosimetry results showed that the radiographer received a total of 4.52 mSv (452 mrem) in March (including this event), while the assistant radiographer received 0.4 mSv (40 mrem) for the same period. The direct cause of this event was residual moisture inside the exposure device locking mechanism that subsequently froze and interfered with the auto-locking mechanism. This was compounded by the failure to ensure that the auto-lock was engaged. No defect was found with the exposure device. Corrective actions included procedure modification and personnel training to test the auto-lock mechanism after every exposure and engage the plunger lock prior to moving an exposure device.

Item Number 170140 - A radiography services company reported that a fire occurred during radiographic operations on 3/9/2017. The radiography crew was working at a refinery and was approximately seven minutes into a 13-minute exposure when a fire started that engulfed the exposure device. One radiographer was immediately sent to notify the Site RSO and plant fire department. The lead radiographer attempted to retract the 2,523 GBq (68.2 Ci) Ir-192 source. The controls would not function and the source remained exposed. The lead radiographer was able to momentarily extinguish the fire. However, the fire reignited and the radiographer exited the area. The radiographers were instructed to extend their boundaries and wait for assistance. The fire department arrived and was able to extinguish the fire from outside the boundaries, using the fire truck as shielding. A retrieval team identified that the source had slid back out of the collimator. Additionally, the drive cable conduit was melted, allowing the drive cable to move freely without the use of the controls. The Site RSO, Corporate RSO, and manufacturer's representative agreed upon a retrieval plan. The drive cable was manually retracted and the source was pulled into the shielded position. Radiation surveys confirmed that the source was shielded and in the locked position. Leak tests were performed on the source and samples were sent overnight to the manufacturer for analysis. The lead radiographer received 54 mrem, two other radiographers received 12 and 13 mrem, the Site RSO received 5 mrem, and the fire fighters received approximately 1.6 mrem. The Minnesota Department of Health investigated the incident. The cause of the fire is still under investigation. However, it was determined that the cause was not due to the radiographers or their equipment.

Item Number 170155 - A radiopharmacy reported that a vehicle fire occurred due to mechanical issues on 3/17/2017 near mile marker 286 on I-76 in Reamstown, Pennsylvania. The vehicle was carrying 79.572718 GBq (2.150614 Ci) of Tc-99m and 40.183739 GBq (1.086047 Ci) of F-18. Pennsylvania Department of Environmental Protection emergency response and radiological health physics staff

responded to the scene. The vehicle was entirely engulfed in flames and allowed to burn itself out. The radiopharmacy personnel at the scene collected contaminated debris and ash, which was returned to their facility for decay. The vehicle was then transported to an isolated storage area, allowed to decay to background, and then released on 3/24/2017. The entire area was surveyed and no residual contamination was identified. This event was classified as an EQP, LAS, and TRS event.

Item Number 170177 - A paper company reported that the source shutter on a fixed nuclear gauge was stuck in the open position at their Georgetown mill. The gauge contained a 3.7 GBq (100 mCi) Cs-137 source. The incident was discovered on 3/22/2017. The company was removing the gauge as part of their annual outage when a survey discovered higher than normal radiation levels. The RSO was contacted and the gauge was moved to the storage area and placed with the shutter face down. During this process, one individual may have been exposed to 19.1 mR; dosimetry results are pending. A gauge repair company was contacted to the service the gauge. They arrived on 3/22/2017 and found that the roll pin connecting the shutter handle to the shutter was broken. Following repair, the gauge was returned to storage for later installation.

Item Number 170185 - A construction materials testing company reported that a moisture/density gauge was damaged by construction equipment on 4/3/2017. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source. The incident occurred at a construction site on US 83 near Garden City, Kansas. The Cs-137 source rod was extended at the time of the incident. The gauge was left unattended by the operator, caught by a plow blade, and dragged. The gauge was torn apart and the Cs-137 source rod was pulled completely out of the gauge and unshielded. Radiation surveys were performed for contamination with negative results. It was confirmed that both sources were intact and not leaking. The gauge was returned to its case and temporary shielding (sand) was used to prevent exposure during transportation back to the company's facility. The operator stated that radiation readings of the gauge in its case were 2 mR/hour at one meter. The gauge was sealed in a concrete bunker. The company returned the gauge to the manufacturer for disposal. The Kansas Department of Health and Environment investigated the incident. Corrective actions included reprimanding involved personnel and providing additional training to prevent recurrence.

Item Number 170284 - A patient received 1,540 cGy (rad) instead of the prescribed 2,000 cGy (rad) during a gamma knife treatment to a single brain lesion on 5/31/2017. The incident involved a gamma knife unit and 201 Co-60 sources, each with an activity of approximately 462.5 GBq (12.5 Ci). Three out of five shots had been delivered when the couch retracted from the treatment position due to a clutch malfunction. Because of uncertainty regarding the repair, the fixation frame was removed from the patient's head and the patient was released. Repairs were completed six hours later. However, the patient elected to not return and complete the procedure. The referring physician was notified on 6/2/2017. The medical facility will work with the manufacturer to determine whether any preventative measures can be taken. This event was classified as an EQP and MED event.

Item Number 170317 - A radiography services company reported a possible overexposure to a radiographer that occurred on 6/23/2017. Operations were being performed at a field site using a 2,997 GBq (81 Ci) Ir-192 source. The radiographer approached the exposure device to disconnect the guide tube. After reaching down to disconnect the guide tube, the radiographer noticed that the guide tube was not completely connected to the device. A radiation dose rate meter was pegged on the 10X scale. The source was then fully retracted. The radiographer stated that his hand was in close proximity to the guide tube for about 10 seconds. The radiographer's self-reading dosimeter revealed 0.52 mSv (52 mrem) following the event. The radiography crews' TLD badges were sent to the processor for analysis. Processing revealed an exposure to the radiographer of 1.98 mSv (198 mrem) DDE for the monitoring period. The company stated on 6/27/2017 that no changes had been seen in the appearance of the radiographer's hands and he had felt no discomfort. A blood sample was sent to REAC/TS for analysis. Calculations indicated that the radiographer received 2.655 cSv (rem) to the hand. Corrective actions included providing additional training to personnel.

Item Number 170384 - A panoramic irradiator licensee reported that two of three source racks containing Co-60 were inoperable on 8/14/2017. Following a 72-hour shutdown, an irradiator restart commenced. Air pressure was applied to raise the source racks. Subsequently, source racks 1 and 3 would not descend into the irradiator pool as designed. This condition existed for approximately 45 minutes until the RSO manually loosened a pipe fitting near the air pressure gauge and bled the air from the rack cylinders, allowing the source racks to descend to the fully shielded position in the pool. The cause of the incident was determined to be condensation and debris in the source hoist valves following the shutdown. All source hoist valves were replaced with new valves and the source racks were satisfactorily tested. The licensee instituted corrective actions by adding annual replacement of the source hoist valves to the maintenance tracking and scheduling program.

Item Number 170427 - A patient only received 6.4% of their prescribed dose during the first of five fractions of a high dose rate (HDR) interstitial brachytherapy treatment of the cervix. The written directive prescribed five fractions of 500 cGy (rad) each, for a total dose of 2,500 cGy (rad) to the patient's cervix. The first fractional treatment was performed on 9/5/2017, but the patient only received 32 cGy (rad), instead of the prescribed 500 cGy (rad). Treatment duration was only 12.1 seconds versus the planned 576.8 seconds. The hospital stated that five separate interlocks were tripped during that first fraction, at which time the manufacturer was contacted. Based on discussions between the medical physics team and the manufacturer, the error was caused by fluid in the catheter that may have contaminated the source and afterloader unit. The treatment was suspended and all use of the HDR afterloader unit was scheduled for 9/7/20017 through 9/9/2017. This event was classified as an EQP and MED event.

Item Number 170435 - A hospital reported a leaking brachytherapy flexible film conformal source that contained 185 MBq (5 mCi) of P-32. The source was used to treat a patient's tumor on the lateral surface of the left eye. Prior to patient treatment on 8/24/2017, the source was wipe tested with no removable contamination detected. At the completion of treatment, the source was removed from the patient and placed into a water bath for shielding. Radiation safety personnel surveyed the patient's treatment area and identified 10,000 cpm or approximately 1,184 Bq (32 nCi). Towels, bowls, water, and other material used during the patient procedure were also radioactively contaminated. Initial investigation revealed no visible damage to the source. The source was transferred to radiation safety and is being held in storage for further investigation. The hospital stated that the patient received their prescribed dose and the physicians do not anticipate any harm to the patient. The hospital will simulate the procedure using a test sample to determine where the leakage and contamination might have occurred. The hospital suspended further treatments with P-32 eye plaques until patient safety concerns have been addressed. This event was classified as an EQP and LKS event.

### 2.7.3 Events Recently Added to NMED That Occurred Prior to FY17

Eleven 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 150350 - A steel manufacturer reported that a scrap metal shipment from a metal recycler set off their radiation monitor alarms on 6/5/2015. A radiation survey revealed 500 mR/hour at two meters. Radiation readings in the cab of the truck were 10 mR/hour. The truck's driver had been in the cab for approximately four hours. The load was secured at the steel manufacturer until Florida Bureau of

Radiation Control (FBRC) personnel arrived on site. The source was identified as a 0.3 GBq (8 mCi) Cs-137 source attached to a broken source rod from a gauge. Radiation surveys revealed 1.5 R/hour on contact. FBRC determined that the source was from a moisture-density gauge that was stolen in 2008 (see NMED Item Number 080471). The 1.48 GBq (40 mCi) Am-Be source was not recovered. This event was classified as an EQP and LAS event.

Item Number 160310 - A radiography services company reported that a radiographer received an unplanned exposure while working in a fabrication shop in Coburn, Colorado, on 6/18/2016. The 2.22 TBq (60 Ci) Ir-192 source was thought to have been retracted into the radiography exposure device, but was hung up in the guide tube. Without using a survey meter, the radiographer approached and handled the guide tube. The estimated dose to the radiographer was 0.5 cSv (rem) to the whole body dose, and 12 cSv (rem) to the extremity. The estimated dose to the assistant radiographer was 0.2 mSv (20 mrem). Dosimetry was submitted to the vendor for processing. The processed dosimeter revealed a whole body exposure of 3.26 mSv (326 mrem). Based on that exposure, the estimated extremity exposure was revised to 72.2 mSv (7.22 rem). The cause of the event was determined to be failure to follow procedures. Corrective actions included reprimanding involved personnel and providing additional training to personnel.

Item Number 170323 - A university reported that an unplanned contamination event occurred as a result of dissolving a 4.63 MBq (125  $\mu$ Ci) Po-210 source, which was part of a static eliminator. Po-210 contamination was discovered when a graduate research assistant was surveying himself upon exiting the laboratory on 12/12/2013. The university's RSO was notified. The laboratory was posted and access was restricted. The contamination caused the restricted area to be closed for more than 24 hours. The laboratory was subsequently thoroughly decontaminated. The cause of the event was failure to follow procedure or wrong procedure used. Corrective actions included providing new training to personnel. This event was classified as an EQP, LAS, LKS, and RLM event.

Item Number 170443 - Five patients received doses that exceeded reportable limits. The patients had been treated using a high dose rate (HDR) afterloader unit and Ir-192 sources with activities ranging from 355.57 to 440.3 GBq (9.61 to 11.9 Ci). An error in the commercial treatment planning software resulted in an actual source step size of 5 mm instead of the planned 2.5 mm. The hospital became aware of the software error when the software vendor notified them on  $\frac{8}{22}/2017$ . All five patients were treated for malignant neoplasm of cervix uteri. The targeted patient area that received reportable radiation dose was the tissue of the upper vaginal wall in each of the five patient cases. The first patient was prescribed to receive a total dose of 2,720 cGy (rad) during four fractions, but only received 2,054.6 cGy (rad) to the intended treatment site, which was 24.46% less than their prescribed dose. The second patient was prescribed to receive a total dose of 3,000 cGy (rad) during five fractions, but only received 2,370 cGy (rad) to the intended treatment site, which was 21% less than their prescribed dose. The third patient was prescribed to receive a total dose of 2,750 cGy (rad) during five fractions, but only received 1,871 cGy (rad) to the intended treatment site, which was 31.96% less than their prescribed dose. The fourth patient was prescribed to receive a total dose of 2,600 cGy (rad) during four fractions, but only received 1,935 cGy (rad) to the intended treatment site, which was 25.58% less than their prescribed dose. The fifth patient was prescribed to receive a total dose of 2,750 cGy (rad) during four fractions, but only received 2,175.6 cGy (rad) to the intended treatment site, which was 20.89% less than their prescribed dose. There were no doses to unintended treatment sites for any of the patients. The authorized user stated that the treatment site for each patient was considered to be the entire reproductive system (ovaries, cervix, and vagina). While it is true that the treatment planning software error resulted in unintended dose to the lower vagina as the source path extended beyond the planned endpoint within the applicator and in some cases started on a return path back into the lower vagina, that tissue was protected to a degree by the fluid-filled sleeve into which the applicator was inserted. The lower vaginal walls were both shielded by the sleeve and were pushed further away from the source. That complicated the dose estimation to that tissue. The authorized user stated that performing a full analysis of the dose to that tissue would take

several weeks and would severely impact therapy schedules. Estimates of the variance of the dose to organs or tissue that were not part of the treatment site were previously made, although that information was not included in the report. The hospital contacted all five patients and their referring physicians. The hospital suspended performing this specific treatment until the software is updated. NMED Item Numbers 170403 and 170404 are related to this issue. This event was classified as an EQP and MED event.

# 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 data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

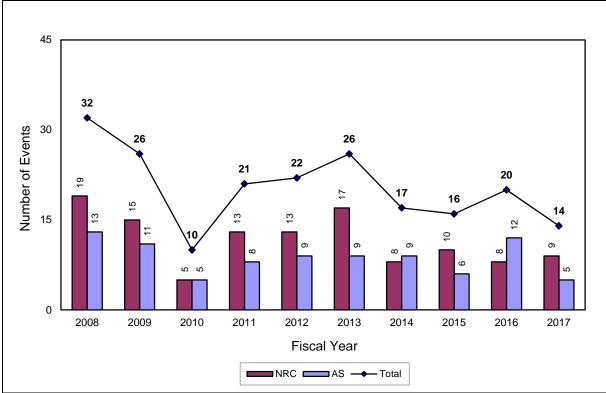


Figure 8. Transportation Events (204 total)

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 FY17 Data

Fourteen TRS events occurred in FY17, two of which were considered significant.

# Significant Events

Item Number 170195 - A radiation safety support company reported that a common carrier delivered a Type 7A 10-gallon drum on 4/13/2017 that had a contact radiation reading of 1.45 R/hour (corrected to 2.83 R/hour) and a Transport Index of 15. Company staff had prepared the shipment at a temporary jobsite in New York City, New York, for shipment to the company's facility in Idaho Falls, Idaho. No radioactive contamination was found on the inside or outside of the package. The package contained five sources, three of which were in a lead pig. The three sources in the lead pig included a 717.8 MBq (19.4 mCi) Cs-137 source, an 851 MBq (23 mCi) Cs-137 source, and a 92.5 MBq (2.5 mCi) Co-60 source. The other two sources (a Ra-226 rod tip and a U-238 source) were packaged and secured separately in the drum and were not involved in this event. Investigation revealed that the three sources in the lead pig had come out of the pig, but were still inside the drum. The lid of the lead pig had been displaced enough

during shipment that the sources were allowed to escape by the time they arrived at the Idaho Falls facility. The pig was not taped or strapped shut to prevent displacement. The common carrier was contacted. NRC concluded that the maximally exposed package handler (a member of the public) could have received an estimated whole body dose of approximately 0.26 mSv (26 mrem). The direct cause of this event was the failure to use a containment system on the lead pig that could be securely closed by a positive fastening device. The root cause of this event was inadequate management oversight over portions of the transportation program. Corrective actions included revision of packaging procedures and personnel training.

Item Number 170230 - On 5/1/2017, a nuclear gauge manufacturer reported receiving a shipment of radioactive sources from a radioactive source manufacturer in which external radiation levels exceeded limits. The 5-gallon shielded drum contained eight Cf-252 sources, each containing an activity of 18.5 MBq (500  $\mu$ Ci). The drum was labeled Yellow III with a transport index of 9.4. Radiation surveys on the top of the drum revealed 4 mSv/hour (400 mrem/hour) neutron and 0.4 mSv/hour (40 mrem/hour) gamma. Surveys on the sides of the drum revealed 0.9 mSv/hour (90 mrem/hour) neutron and 0.18 mSv/hour (18 mrem/hour) gamma. Surveys on the bottom of the drum revealed 0.2 mSv/hour (20 mrem/hour) neutron and 0.03 mSv/hour (3 mrem/hour) gamma. With the drum placed on its side, surveys on top of the drum revealed 4.4 mSv/hour (440 mrem/hour) neutron. Wipes of the drum revealed less than minimum detectable levels. The drum was shielded with polyethylene and cadmium. The drum was opened and a polyethylene bag containing the sources was sitting on top of the shield plug about two inches from the top of the drum. The sources were not covered by any shielding. The North Carolina Department of Health and Human Services (NCDHHS), source manufacturer, and common carrier were notified on 5/1/2017. NCDHHS investigation revealed that the source manufacturer's chemist loaded the sources into the drum. However, the top shielding plug did not fit properly due to the quantity of sources, so he left the plug out but did not inform the source manufacturer's shipper. The shipper did not witness the loading, did not open the Type A container to verify the final assembly, misread his survey meter readings, and incorrectly recorded the transport index. Corrective actions included retraining the shipper on DOT radioactive material requirements and on the use of radiation survey instruments. Loading instructions for the Type A container were developed to indicate the maximum load, how to take readings using various survey meters, and requiring that the shipper supervise the loading of sources. NCDHHS contacted the common carrier regarding the possibility of overexposures during transit. The carrier stated that due to the constant movement of the shipped item and logistics of the shipping route, it would be near impossible to provide a dose assessment with any accurate and meaningful results.

#### Events of Interest

Item Number 170155 - A radiopharmacy reported that a vehicle fire occurred due to mechanical issues on 3/17/2017 near mile marker 286 on I-76 in Reamstown, Pennsylvania. The vehicle was carrying 79.572718 GBq (2.150614 Ci) of Tc-99m and 40.183739 GBq (1.086047 Ci) of F-18. Pennsylvania Department of Environmental Protection emergency response and radiological health physics staff responded to the scene. The vehicle was entirely engulfed in flames and allowed to burn itself out. The radiopharmacy personnel at the scene collected contaminated debris and ash, which was returned to their facility for decay. The vehicle was then transported to an isolated storage area, allowed to decay to background, and then released on 3/24/2017. The entire area was surveyed and no residual contamination was identified. This event was classified as an EQP, LAS, and TRS event.

### 2.8.3 Events Recently Added to NMED That Occurred Prior to FY17

No 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. 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.

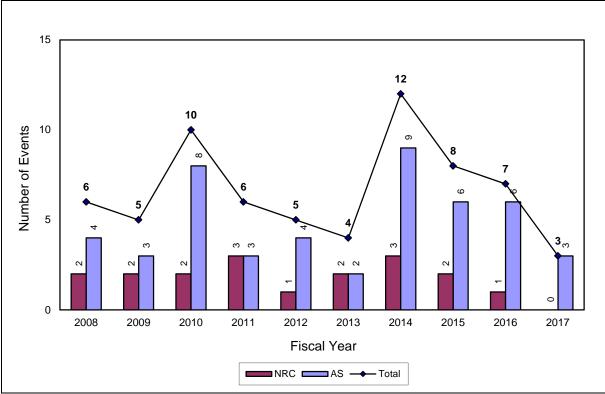


Figure 9. Other Events (66 total)

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 FY17 Data

Three OTH events occurred in FY17, none of which were considered significant.

#### Significant Events None

### Events of Interest

Item Number 170245 - A chemical company reported that three individuals performed work on 3/2/2017 near two fixed nuclear gauges. Each gauge contained a 3.7 GBq (100 mCi) Cs-137 source. One of the three individuals removed the signs and hand guards from the two fixed gauges. The three individuals then removed the insulation and coating from the vessel that the gauges were mounted to. The individuals reached between the sources and the vessel during this process. The company determined that the individuals exceeded 0.02 mSv in any hour (2 mrem in any hour), but did not exceed TEDE exposures of 1 mSv (100 mrem). One of the individuals initially visited a doctor and claimed that he had been

exposed to Cs-137. The company obtained bioassays from two individuals, the results of which were negative. The Texas Department of State Health Services performed an on-site investigation on 5/5/2017. It was determined that the individuals involved had not received adequate training to prevent the event. Corrective actions included revising the training program, changing the design of the gauge security system, and modifying procedures.

Item Number 170325 - A radioactive source manufacturer reported a security incident that involved their radioactive sealed source manager, who is in the Trustworthy and Reliability Program. Specifically, the manager downloaded a large amount of confidential information, including an inventory of radioactive material, from the manufacturer's server on 4/25/2017. The manager's employment was terminated on 5/3/2017. The Houston Police Department and FBI were notified of the incident. During an exit interview on 5/4/2017, the manager admitted to downloading procedures, security information, and inventories to start his own company. No actual theft of radioactive material occurred. The portable hard drive containing the downloaded information was returned to the manufacturer on 5/5/2017. A lawsuit and a temporary restraining order were filed against the manager. The manufacturer hired an onsite armed security guard during normal working hours for 30 days. The Texas Health and Human Services Agency performed an onsite investigation on 6/28/2017 and determined that all material was accounted for. The manufacturer changed their computer network to stop any future downloads of information to a flash drive or portable hard drive. The FBI determined that no further investigation was warranted.

Item Number 170532 - A radiography services company reported that the computer display for 16 security cameras went blank/offline for 50 minutes on 9/22/2017. The company contacted the information technology (IT) company that provides their computer system services. The IT company determined that someone had hacked into the computer system at the main video surveillance company, which affected the video at client facilities (including the radiography company). The video system was the only unit affected. The breach did not come through the main computer server, nor did it affect any of the vault system communication lines at the radiography company. The Texas Department of State Health Services (TDSHS) responded to the radiography company site on 10/4/2017. TDSHS inspected the security system and the vault area. They agreed that the breach was to the main video surveillance company made corrections to their system to eliminate future breaches. Upgrades in firewalls and the alerting system were completed, as well as password changes to prevent recurrence. The security system has back up power from batteries and a generator. There was no breach in the camera security system.

### 2.9.3 Events Recently Added to NMED That Occurred Prior to FY17

One OTH 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 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  $10 \times \text{or } 1,000 \times \text{the } 10$  CFR Part 20 Appendix C quantity is based on the aggregate quantity of licensed material.

Primary LAS Reporting Requirements	Reporting Requirement Summary
20.2201(a)(1)(i)	Aggregate activity $\geq$ 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

#### Table A-1. Primary LAS Reporting Requirements

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.

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.

Table A-2. Secondary LAS Reporting Requirements

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.

MED Reporting Requirements	Reporting Requirement Summary
35.3045(a)(1)(i)	Total dose delivered that differs from the prescribed dose by 20% or more; and differs from the prescribed dose by more than $0.05 \text{ Sv}$ (5 rem) EDE, $0.5 \text{ Sv}$ (50 rem) to an organ or tissue, or $0.5 \text{ Sv}$ (50 rem) SDE.
35.3045(a)(1)(ii)	Total dosage delivered differs from prescribed 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.
35.3045(a)(1)(iii)	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.
35.3045(a)(2)(i)	Administration of a wrong radioactive drug containing byproduct material 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.
35.3045(a)(2)(ii)	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)(2)(iii)	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)(2)(iv)	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)(2)(v)	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)(3)	Dose to the skin, organ, or tissue, other than the treatment site, that exceeds the prescribed dose by $0.5 \text{ Sv}$ (50 rem) and 50% or more (excluding permanently implanted seeds that migrated from the treatment site).
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.

Table A-3. MED Reporting Requirements

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.

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.

Table A-4. EXP Reporting Requirements

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.

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.

Table A-5. RLM Reporting Requirements

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.

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

Table A-6. LKS Reporting Requirements

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  $\leq 100 \mu \text{Ci}$  of other beta and/or gamma emitting material,
- Sources containing  $\leq 10 \mu \text{Ci}$  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  $0.005 \ \mu\text{Ci}$  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.

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.
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.

Table A-7. EQP Reporting Requirements

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.
	salety 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.

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.

Table A-8. TRS Reporting Requirements

### 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  $\alpha$  and  $\beta$  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,  $\sigma^2$ . 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,  $\sigma 2$ .

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  $\alpha$  and  $\beta$  is the method of least squares (LS). In this method,  $\alpha$  and  $\beta$  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

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

$$\hat{\alpha} = \overline{y} - \hat{\beta}\overline{x} , \qquad (B-3)$$

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

$$\hat{y} = \hat{\alpha} - \hat{\beta}x, \qquad (B-4)$$

and an estimate of  $\sigma$  is

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

#### **Testing for Trend**

A trend exists whenever the true slope,  $\beta$ , is not zero. We start the analysis with the idea that  $\beta$  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  $\alpha$  and  $\beta$ . 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

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

$$SSE + SSR = SST$$
, (B-8)

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

$$SST = \sum_{i=1}^{n} (y_i - \bar{y})^2$$
. (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  $y = \overline{y}$ . *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  $\beta$  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,  $\overline{y}$ , 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

$$F = \frac{(n-2)r^2}{1-r^2}$$
(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  $\beta$  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 95<sup>th</sup> percentile of the *F*(1,11) distribution is 4.84. Since 163.3 far exceeds the upper 95<sup>th</sup> *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 95<sup>th</sup> 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.

	Category 1		Category 2		Category 3		Category 4		Category 5	
Radionuclide	TBq	Ci <sup>1</sup>	ТВq	Ci <sup>1</sup>						
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
lr-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

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

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.

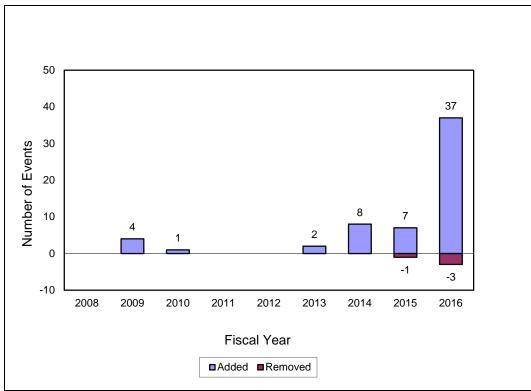


Figure D-1. Changes to All NMED Event Data

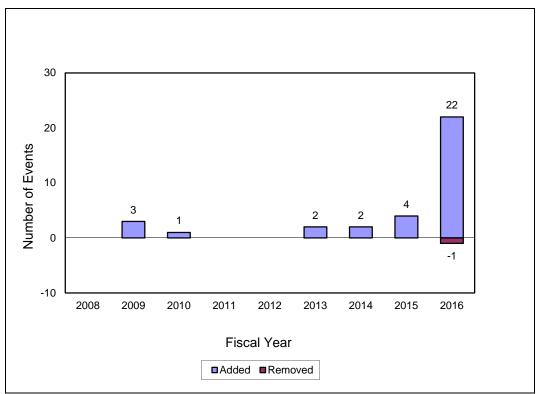


Figure D-2. Changes to LAS Data

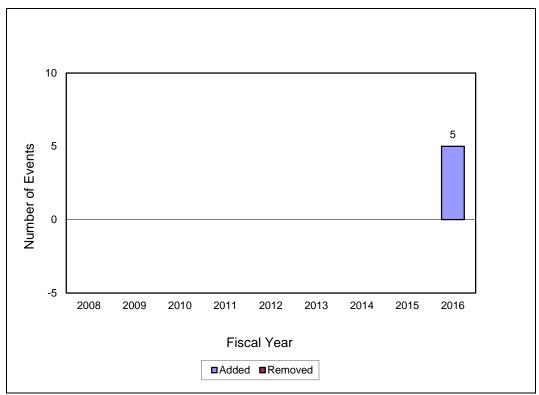


Figure D-3. Changes to MED Data

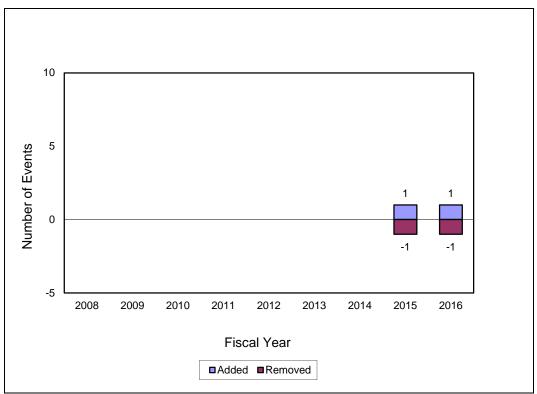


Figure D-4. Changes to EXP Data

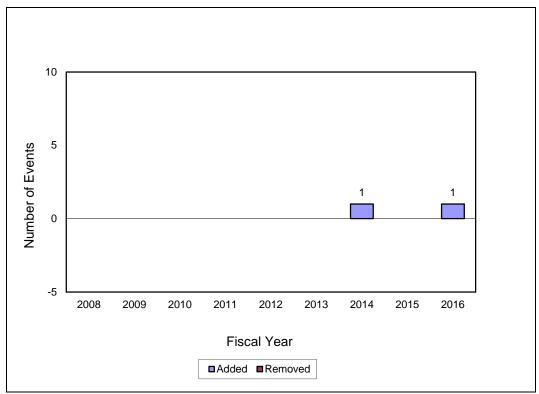


Figure D-5. Changes to RLM Data

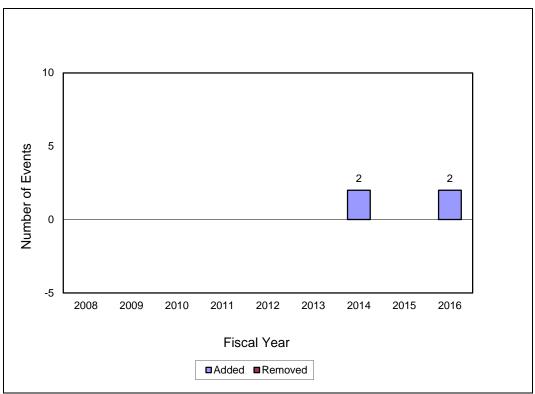


Figure D-6. Changes to LKS Data

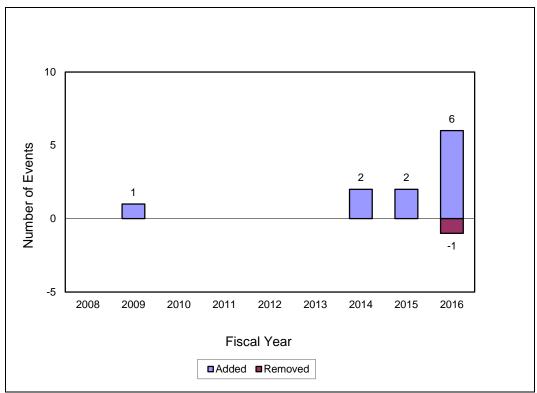


Figure D-7. Changes to EQP Data

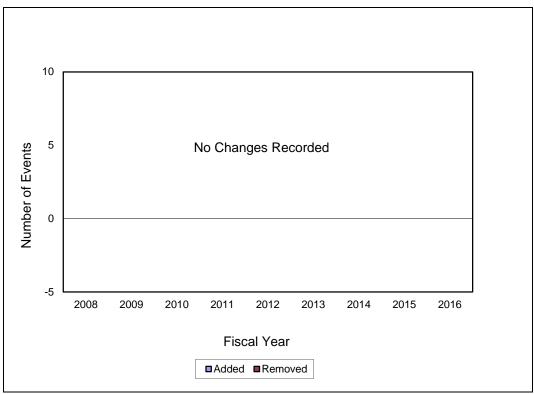


Figure D-8. Changes to TRS Data

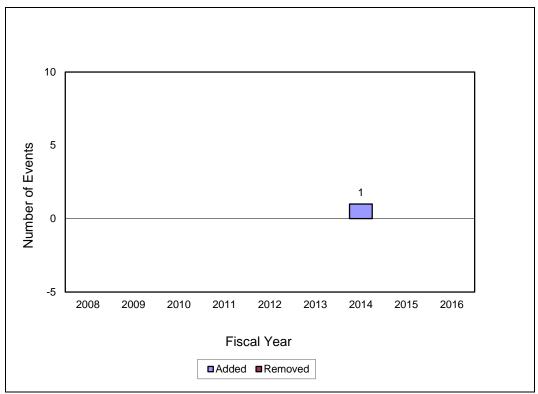


Figure D-9. Changes to OTH Data