

APPENDIX C

STANDARD CITATIONS

This Appendix includes standard citations to be used in preparing enforcement actions. These standard citations are available as a computer file and can be electronically transmitted either from the Office of Enforcement or from the Regional Enforcement Coordinators.

Requirement sections are identified by bold type and are followed by one or more examples of violation ("contrary to") sections.

The following is a key to the notation used in the standard citations:

Symbol	Meaning
(_____) or _____	Fill in the blank with the appropriate information
()	Text within parentheses indicates the optional use of an alternative word or an optional choice or the plural form of the word preceding the parentheses.
[]	Text within brackets indicates narrative guidance that should be followed in terms of addressing specific elements that should be included in the particular document.
“ ”	Text within quotes indicates a suggested sentence or language.

TABLE OF CONTENTS

APPENDIX C STANDARD CITATIONS	i
TABLE OF CONTENTS	ii
10 CFR PART 19 NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS.....	1
10 CFR 19.11(a)	1
10 CFR 19.11(b)	1
10 CFR 19.11(c).....	1
10 CFR 19.12(a)	1
10 CFR PART 20 STANDARDS FOR PROTECTION AGAINST RADIATION PERMISSIBLE DOSES, LEVELS AND CONCENTRATIONS	3
10 CFR 20.1201(a)(1)(i).....	3
10 CFR 20.1201(a)(1)(ii).....	3
10 CFR 20.1201(a)(2)(ii).....	3
10 CFR 20.1301(a)(2).....	4
10 CFR 20.1501	4
10 CFR 20.1502(a)(3).....	5
10 CFR 20.1601(a)	5
10 CFR 20.1601(b)	6
SECURITY	7
10 CFR 20.1801	7
10 CFR 20.1802.....	7
10 CFR 20.1902(a)	7
10 CFR 20.1902(e)	7
10 CFR 20.1904(a)	8
10 CFR 20.1904(a)	8
10 CFR 20.1904(b)	8
10 CFR 20.1906(b)	9
10 CFR 20.1907(c).....	9
WASTE DISPOSAL	10
10 CFR 20.2001(a)	10
RECORDS, REPORTS, AND NOTIFICATIONS.....	10

10 CFR 20.2103(a)	10
10 CFR 20.2106(a)	10
10 CFR 20.2108	11
10 CFR 20.2206	11
10 CFR PART 30 DOMESTIC LICENSING OF BYPRODUCT MATERIAL CITATIONS FOR ACTIVITIES OR LOCATIONS NOT AUTHORIZED BY A LICENSE	12
10 CFR 30.3	12
10 CFR 30.9(a)	12
10 CFR 30.9(a)	12
10 CFR 30.34(c)	13
10 CFR 30.34(c)	13
10 CFR 30.34(c)	13
PORTABLE GAUGE SECURITY	14
10 CFR 30.34(i)	14
DECOMMISSIONING	16
10 CFR 30.35(a)	16
10 CFR 30.35(b)	16
10 CFR 30.35(c)(4)	16
10 CFR 30.36(d)	17
10 CFR 30.36(d)	17
10 CFR 30.36(g)(1)	18
10 CFR 30.36(e)(1)	19
10 CFR 30.36(h)	19
TRANSFER OF MATERIAL	20
10 CFR 30.41(a) and (b)(5)	20
10 CFR 30.41(c)	20
10 CFR 30.51(a)	20
10 CFR PART 31 GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL	21
10 CFR 31.5(c)(1)	21
10 CFR 31.5(c)(2)	21
10 CFR 31.5(c)(3)	21
10 CFR 31.5(c)(4)	22

10 CFR 31.5(c)(6)	22
10 CFR 31.5(c)(8)	23
10 CFR 31.11(c)(1)	23
10 CFR PART 34 RADIOGRAPHY.....	24
10 CFR 34.23(a)	24
10 CFR 34.25(a)	24
10 CFR 34.25(b)(1)	24
10 CFR 34.27(c)(1)	25
10 CFR 34.27(e)	25
10 CFR 34.29(a)	25
10 CFR 34.31(a)	25
10 CFR 34.33(a)	26
10 CFR 34.41(a)	26
10 CFR 34.41(a)	26
10 CFR 34.43(a)	26
10 CFR 34.43(b)(1)	27
10 CFR 34.43(b)(2)	27
10 CFR 34.43(b)(3)	27
10 CFR 34.43(b)(4)	28
10 CFR 34.43(c)(1)	28
10 CFR 34.43(c)(2)	28
10 CFR 34.43(c)(3)	29
10 CFR 34.43(e)(1)	29
10 CFR 34.43(f)	29
10 CFR 34.46	30
10 CFR 34.47(a)	30
10 CFR 34.47(b)	30
10 CFR 34.47(c)	31
10 CFR 34.47(d)	31
10 CFR 34.49(b)	31
10 CFR 34.51	31
10 CFR 34.53	32
10 CFR 34.67	32
10 CFR 34.71	32

10 CFR 34.85.....	33
10 CFR PART 35 MEDICAL USE.....	34
10 CFR 35.24(a).....	34
10 CFR 35.24(b).....	34
10 CFR 35.24(f).....	34
10 CFR 35.24(g).....	35
10 CFR 35.24(h).....	35
10 CFR 35.27(a)(1).....	35
10 CFR 35.27(a)(2).....	35
10 CFR 35.27(b)(1).....	36
10 CFR 35.27(b)(2).....	36
10 CFR 35.41(a).....	36
10 CFR 35.41(c).....	37
10 CFR 35.60(a).....	37
10 CFR 35.60(b).....	37
10 CFR 35.60(c).....	37
10 CFR 35.61(a).....	38
10 CFR 35.63(a).....	38
10 CFR 35.63(b).....	38
10 CFR 35.63(c).....	38
10 CFR 35.615(a).....	39
10 CFR 35.615(b).....	39
10 CFR 35.3045(a).....	39
10 CFR 35.3045(c).....	40
10 CFR PART 71 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL.....	41
10 CFR 71.3.....	41
10 CFR 71.14(b).....	41
CITATIONS FOR FAILURE TO FOLLOW DOT REGULATIONS.....	42
10 CFR 71.5(a).....	42
10 CFR 71.17.....	42
10 CFR PART 150 EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274.....	43
RECIPROCITY.....	43

10 CFR 150.20(a)	43
10 CFR 150.20(b)(1)	43
49 CFR PART 172 HAZARDOUS MATERIALS	44
SHIPPING PAPERS	44
49 CFR 172.200(a)	44
49 CFR 177.817(a)	44
EMERGENCY RESPONSE TELEPHONE NUMBER.....	45
49 CFR 172.201(d)	45
49 CFR 172.202(a) and (b)	45
49 CFR 172.203(c)(2)	45
49 CFR 172.203(d)	46
49 CFR 172.310.....	46
49 CFR 172.312.....	46
49 CFR 172.403.....	47
49 CFR 172.403(b)	48
49 CFR 172.403(b)	48
PROHIBITED PLACARDING.....	49
49 CFR 172.502(a)	49
49 CFR 172.504.....	49
EMERGENCY RESPONSE TELEPHONE NUMBER.....	50
49 CFR 172.600	50
49 CFR 172.602.....	50
49 CFR 172.602(c).....	51
49 CFR 172.604.....	51
HAZMAT TRAINING REQUIREMENTS.....	52
49 CFR 172.702.....	52
49 CFR 172.704(a)	52
49 CFR 172.704(d)	52
49 CFR PART 173 SHIPPERS: REQUIREMENTS FOR SHIPMENTS AND PACKAGING ...	54
49 CFR 173.25.....	54
49 CFR 173.411(c).....	54
49 CFR 173.415(a)	55

49 CFR 173.421	55
49 CFR 173.424	56
49 CFR 173.475	57
49 CFR 173.427(a)(6)	57
49 CFR 173.475	58
49 CFR 173.475	58
49 CFR 173.448(a)	59
49 CFR 173.466	59
49 CFR 173.461	59
49 CFR 173.475	59
49 CFR 173.475	59
49 CFR 173.476(a)	60
49 CFR PART 177 CARRIAGE BY PUBLIC HIGHWAY	61
49 CFR 177.817(e)	61
49 CFR 177.834(a)	61
49 CFR 177.842	61

THIS PAGE INTENTIONALLY LEFT BLANK

10 CFR PART 19 NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS

10 CFR 19.11(a) requires that the licensee post current copies of Parts 19 and 20; the license, license conditions, and documents incorporated into the license; license amendments; operating procedures applicable to licensed activities; any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to subpart B of part 2; and any response from the licensee.

10 CFR 19.11(b) allows the licensee to post a notice which describes the documents identified in 19.11(a), indicating where such documents may be examined, if posting of these documents is not practical.

10 CFR 19.11(c) requires that the licensee post NRC Form 3, "Notice to Employees," dated August 1997; or, within 30 days of receiving a revised version, later versions that supersede the August 1997 form.

Contrary to the above, on (date), the licensee did not post (specify which documents or forms were not posted).

This is a Severity Level _____ violation (Section 6.3).

NOTE: 10 CFR 19.12 pertains specifically to training to protect personnel working in or frequenting a restricted area from exposure to radiation. There must be a relationship between the lack of training and the potential exposure of personnel to radiation before this citation can be used.

10 CFR 19.12(a) requires, in part, that all individuals who in the course of their employment are likely to receive in a year an occupational dose in excess of 100 mrem (1mSv) shall be kept informed of the storage, transfer, and use of radiation or radioactive material; instructed in the health protection problems associated with exposure to radiation and/or radioactive material; instructed in precautions and procedures to minimize exposure to radioactive materials, and in the purpose and functions of protective devices employed; instructed of their responsibility to promptly report to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material; and, instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material.

Contrary to the above, as of (date), individuals who were working in (location), a restricted area, had not been instructed in the applicable provisions of the regulations

and the conditions of the license. Specifically, (describe what information or instruction had not been provided).

This is a Severity Level _____ violation (Section 6.3).

10 CFR PART 20 STANDARDS FOR PROTECTION AGAINST RADIATION PERMISSIBLE DOSES, LEVELS AND CONCENTRATIONS

10 CFR 20.1201(a)(1)(i) requires, with exceptions not applicable here, that the licensee control the occupational dose to individual adults to an annual dose limit of 5 rems total effective dose equivalent.

Contrary to the above, the licensee did not limit the annual occupational dose to an adult (identify the worker, e.g., "technologist") to 5 rems, total effective dose equivalent. Specifically, the individual received (specify amount) rems, total effective dose equivalent, for the period (date) to (date).

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1201(a)(1)(ii) requires, with exceptions not applicable here, that the licensee control the occupational dose to individual adults such that the sum of the deep-dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye does not exceed an annual dose limit of 50 rems.

Contrary to the above, the licensee did not limit the annual dose to the (identify the organ or tissue) of an adult (identify the worker, e.g., "technologist") to 50 rems. Specifically, for the period (date) to (date), the individual received (specify amount) rems deep-dose equivalent and (specify amount) rems committed dose equivalent to the (identify the organ or tissue) for a sum of (specify amount) rems.

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1201(a)(2)(ii) requires, with exceptions not applicable here, that the licensee control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rems shallow-dose equivalent.

Contrary to the above, the licensee did not limit the annual dose to the (skin)/ (extremity) of an adult (identify the worker, e.g., "technologist") to 50 rems shallow-dose equivalent. Specifically, the individual received (specify amount) rems shallow-dose equivalent to the (identify the site, e.g., "skin", "left hand", etc.) for the period (date) to (date).

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1301(a)(2) requires that the licensee conduct operations so that the dose in any unrestricted area from external sources does not exceed 2 millirem in any one hour.

Contrary to the above, on (date), licensee operations resulted in a dose of (specify amount) millirem in one hour in (identify the area, e.g., "an employee lunch room"), an unrestricted area.

This is a Severity Level _____ violation (Section 6.7).

CITATIONS FOR FAILURE TO MAKE SURVEYS: Citations against 10 CFR 20.1501 should include, in the first paragraph, the definition of survey in 10 CFR 20.1003, i.e., *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. Then list the specific citations as subheadings, without repeating the initial paragraph. (Note: All survey citations issued under §20.1501 are contingent on referencing some other section of the Part 20 regulations. This does not mean that noncompliance with that other section is necessary.)

10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Contrary to the above, as of (date), the licensee did not make surveys to assure compliance with 10 CFR 20. , which limits radiation exposure to (specify). Specifically, (briefly describe the specific circumstances. If specific dates are known or can be determined, they should be included in the description of the circumstances).

This is a Severity Level _____ violation (Section 6.7).

or

Contrary to the above, as of (date), the licensee did not make surveys to assure compliance with 10 CFR 20. , which limits radiation levels (briefly describe the specific circumstances. If specific dates are known or can be determined, they should be included in the description of the circumstances).

This is a Severity Level _____ violation (Section 6.7).

or

Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.2001(a), which describes the authorized means of disposing of licensed material. Specifically, on (date), the licensee did not perform a survey before disposing of (specify), which contained (nuclide(s)) as normal, non-radioactive waste.

This is a Severity Level _____ violation (Section 6.7).

or

Contrary to the above, as of (date), the licensee did not make surveys to assure compliance with 10 CFR 20.2003(a), which limits the disposal of licensed material by release into a sanitary sewerage system. Specifically, (briefly describe the specific circumstances. If specific dates are known or can be determined, they should be included in the description of the circumstances).

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1502(a)(3) requires, in part, that each licensee supply and require the use of individual monitoring devices by individuals entering a high or very high radiation area.

Contrary to the above, on (date), the licensee did not (supply) / (require the use of) an individual monitoring device by a (identify the worker, e.g., "technologist") who entered the (identify the area), a high radiation area with a radiation dose rate of approximately (specify amount) rem in one hour at 30 centimeters from the (radiation source) / (surface that the radiation penetrated).

This is a Severity Level _____ violation (Section 6.7).

or

Contrary to the above, on (date), the licensee did not (supply) / (require the use of) an individual monitoring device by a (identify the worker, e.g., "technologist") who entered the (identify the area), a very high radiation area with a radiation dose rate of approximately (specify amount) rads in one hour at one meter from the (radiation source) / (surface that the radiation penetrated).

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1601(a) requires, with exceptions not applicable here, that the licensee ensure that each entrance to a high radiation area has one or more of the following features: (1) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep- dose equivalent of 0.1 rem in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates; (2) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or (3) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

10 CFR 20.1601(b) provides that, in place of the controls required by 10 CFR 20.1601(a) for a high radiation area, a licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

Contrary to the above, as of (date), the entrance to the (identify the area, e.g., by room number, location, etc.), a high radiation area with a radiation dose rate of approximately millirem in one hour at 30 centimeters from the (radiation source) / (surface that the radiation penetrated), was not controlled by any of the methods described in 10 CFR 20.1601(a) or (b).

This is a Severity Level _____ violation (Section 6.7).

SECURITY

NOTE: As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on (date), the licensee did not secure from unauthorized removal or limit access to (specify the type and amount of licensed material) located in (identify the area), which is (a controlled area) / (an unrestricted area).

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on (date), the licensee did not (control/maintain constant surveillance) of (specify the type and amount of licensed material) located in (identify the area), which is (a controlled area) / (an unrestricted area).

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1902(a) requires that the licensee post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

Contrary to the above, as of (date), the (identify the area), a radiation area with a radiation dose rate of approximately (millirem) in one hour at 30 centimeters from the (radiation source) / (surface that the radiation penetrated) was not posted with a sign bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1902(e) requires that the licensee post each area or room in which certain amounts of licensed material, specified in §20.1902(e), are used or stored, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Contrary to the above, on (date), the (identify the room), an area or room in which (specify radionuclide and approximate quantity) was (used) / (stored), was not posted with a conspicuous sign or signs bearing the radiation symbol and the words

"CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1904(a) requires the licensee to ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, etc.) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, on (date), a container of (specify the licensed material) did not bear a label that identified the radionuclide(s) or the quantity of radioactivity, nor did it otherwise bear sufficient information to permit individuals handling or using the container, or working in the vicinity of the container, to take precautions to avoid or minimize exposure.

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1904(a) requires licensees to ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, etc.) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, on (date), a container of (specify the licensed material) did not bear a label that identified the radionuclide(s) or the quantity of radioactivity, nor did it otherwise bear sufficient information to permit individuals handling or using the container, or working in the vicinity of the container, to take precautions to avoid or minimize exposure.

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1904(b) requires that, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, each licensee remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

Contrary to the above, on (date), the licensee transferred empty uncontaminated containers labeled as containing (specify the licensed material) to the non-radioactive trash without first removing or defacing the radioactive material label or otherwise indicating that the containers no longer contained radioactive material.

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.1906(b) requires each licensee to monitor the external surfaces packages labeled with a Radioactive White 1, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71.

10 CFR 20.1907(c) requires licensees to perform the monitoring required by paragraph (b) above, as soon as practicable, but not later than 3 hours after receipt of the package if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Contrary to the above, on (date), the licensee received a package labeled with a Radioactive (White I) / (Yellow II) / (Yellow III) label (during working hours) / (after working hours), the package was not exempt from the monitoring requirement for (radioactive contamination) / (radiation levels), and the licensee did not perform the required monitoring. Specifically, the package received by the licensee contained (specify the radionuclide and approximate quantity) in (specify) form.

This is a Severity Level _____ violation (Section 6.7).

or

Contrary to the above, on (date, time), the licensee received a package labeled with a Radioactive (White I) / (Yellow II) / (Yellow III) label (during working hours) / (after working hours), the package was not exempt from the monitoring requirement for (radioactive contamination) / (radiation levels), and the licensee did not perform the required monitoring within 3 hours (after receipt) / (from the beginning of the next working day). Specifically, the package received by the licensee contained (specify the radionuclide and approximate quantity) in (specify) form, and the licensee did not monitor the package until (date, time).

This is a Severity Level _____ violation (Section 6.7).

WASTE DISPOSAL

10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by specified procedures.

Contrary to the above, on (date) , the licensee disposed of (specify the type and amount of licensed material) by releasing this material to (specify how material was disposed of that is not specified in this section) , a method not authorized by §20.2001.

This is a Severity Level_____violation (Section 6.7).

RECORDS, REPORTS, AND NOTIFICATIONS

10 CFR 20.2103(a) requires that each licensee maintain records of the results of surveys and calibrations required by § § 20.1501 and 20.1906(b). The licensee shall retain these records for three years after the record is made.

Contrary to the above, as of (date) , the licensee did not maintain records of the results of (surveys) / (calibrations) performed on (date(s)) and these (surveys) / (calibrations) were required by (§20.1501) / (§20.1906(b)). This is a Severity Level__violation (Section 6.7).

10 CFR 20.2106(a) requires, in part, that each licensee maintain records of doses received by all individuals for whom monitoring was required pursuant to §20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions.

Contrary to the above, as of (date) , the licensee did not maintain records of doses received by a (identify the individual, e.g., "technologist") , an individual for whom monitoring was required pursuant to §20.1502.

This is a Severity Level_____violation (Section 6.7).

or

Contrary to the above, as of (date) , the licensee did not maintain records of doses received by a (identify the individual, e.g., "health physics technician") , an individual for whom monitoring was required (during a planned special exposure) / (during an accident) / (during emergency conditions) that occurred on (date) .

This is a Severity Level_____violation (Section 6.7).

10 CFR 20.2108 requires that each licensee maintain records of the disposal of licensed materials made under § § 20.2002, 20.2003, 20.2004, 20.2005, Part 61, and disposal by burial in soil, including burials authorized before January 28, 1981.

Contrary to the above, on (date(s)), the licensee disposed of (specify the type and amount of licensed material) by (method of disposal¹), and the licensee did not maintain a record of these disposal(s).

This is a Severity Level _____ violation (Section 6.7).

10 CFR 20.2206 requires that the licensees identified in paragraph (a), submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by 10 CFR 20.1502 during that year, on or before April 30 of each year.

Contrary to the above, although the licensee is subject to the reporting requirement in 10 CFR 20.2206, as of (date), the licensee did not submit the required report for calendar year(s)_____.

This is a Severity Level _____ violation (Section 6.7).

¹ For location-specific disposals such as burial, if the disposal location is known or can be determined, it should be specified in the violation.

**10 CFR PART 30 DOMESTIC
LICENSING OF BYPRODUCT
MATERIAL CITATIONS FOR ACTIVITIES
OR LOCATIONS NOT AUTHORIZED BY
A LICENSE**

NOTE: If a non-licensee conducts activities for which a license is required, use the following citation.

10 CFR 30.3 requires, in part, that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations.

Contrary to the above, on (date) , (name of person or corporate entity) (possessed)/
(used) (nuclide) without a valid NRC license, and was not exempt from the requirements for a license.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

Contrary to the above, the licensee did not provide to the Commission information that was complete and accurate in all material respects. Specifically, on (date), [Specify the information that was provided that was not complete and/or accurate]. This information was material because [Briefly describe why the information was material].

This is a Severity Level _____ violation (Section 6.3I).

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee, or information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above, on (date), information provided by licensee's (title of employee) to an NRC inspector was inaccurate in that (employee), in response to the inspector's questions regarding __, stated that [Briefly describe what was stated.] This statement was not accurate in that [Briefly describe why the statement was not accurate]. This statement was material because [Briefly describe why the statement was material].

This is a Severity Level _____ violation (Section 6.3I).

NOTE: If an activity has been conducted by a licensee which is not authorized by the license, use the first or second of the three citations that follow for 10 CFR 30.34(c), as appropriate. If an activity has been conducted by a licensee at a place not authorized by the license, use the third of the following three citations. If an Agreement State licensee conducts an activity in NRC jurisdiction without filing NRC Form-241, refer to the citations for 10 CFR Part 150.

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license.

Condition ___ of License No. _____ requires that licensed material be used only at__.

Contrary to the above, on (date), the licensee possessed (specify amount and type of licensed material) at [Indicate location of material], a location not authorized by the license.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license.

Condition ___ of License No. _____ limits the use of licensed materials to (specify the use(s)).

Contrary to the above, on (date), the licensee used (byproduct material) for (specify the use), a use not authorized by the license.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct material to the locations and purposes authorized by the license.

Contrary to the above, on (date), the licensee did not confine its (possession) / (use) of byproduct material to the location(s) authorized by the license. Specifically, the licensee (possessed) / (used) (byproduct material) at (specify the location), a location not authorized by the license.

This is a Severity Level _____ violation (Section 6.3).

PORTABLE GAUGE SECURITY

NOTE: When citing portable gauge security violations in which no tangible barrier is used to prevent unauthorized removal, cite the applicable Part 20 and Part 30 regulations. Specifically, include both requirements (i.e., 10 CFR 20.1801/1802 and 10 CFR 30.34(i)) but only 1 “contrary to” statement. This format will only result in one violation. Also, the routine practice of only citing 10 CFR 30.34(i) for cases in which a single barrier is used would continue.

10 CFR 30.34(i) requires that each portable gauge licensee use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

Contrary to the above, on (date), the licensee did not use a minimum of two independent physical controls that form tangible barriers to secure (a) portable gauge(s) from unauthorized removal, when the portable gauge(s) (was/were) not under the control and constant surveillance of the licensee. Specifically, (briefly describe the specific circumstances, e.g., “(a) gauge(s) (was/were) secured with only one tangible barrier to prevent unauthorized removal.”)

This is a Severity Level ____ violation (Section 6.3).

IF citing 10 CFR 30.34(i) using 10 CFR 20.1802, THEN:

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

10 CFR 30.34(i) requires that each portable gauge licensee use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

Contrary to the above, on (date), the licensee did not secure from unauthorized removal or access, by using a minimum of two independent physical controls that form tangible barriers, licensed material in (a) portable gauge(s) that (was/were) stored in a controlled or unrestricted area and not under the control and constant surveillance of the licensee. Specifically, the licensee (briefly describe the specific circumstances, e.g., “stored the gauge in an unlocked shipping container when not under control and constant surveillance of licensee personnel. The gauge was not secured to the container using any tangible barriers, and the shipping container was accessible by members of the public.”)

This is a Severity Level _____ violation (Section 6.3)

IF citing 10 CFR 30.34(i) using 10 CFR 20.1802, THEN:

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

10 CFR 30.34(i) requires that each portable gauge licensee use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

Contrary to the above, on (date), the licensee did not maintain control and constant surveillance of, or use a minimum of two independent physical controls that form tangible barriers to secure from unauthorized removal, licensed material in (a) portable gauge(s) that (was/were) not in storage. Specifically, (briefly describe the specific circumstances, e.g., "(a) gauge(s) (was/were) left unattended and uncontrolled at a temporary jobsite.")

This is a Severity Level _____ violation (Section 6.3)

DECOMMISSIONING

NOTE: For a violation of 30.35(c)(4), first determine whether the licensee is subject to 10 CFR 30.35(a) or (b). Use one of the following two citations, as appropriate, followed by the citation for 10 CFR 30.35(c)(4).

10 CFR 30.35(a) requires each applicant for a specific license authorizing possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 105 times the applicable quantities set forth in 10 CFR Part 30 Appendix B to submit a decommissioning funding plan as described in 10 CFR 30.35(e). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 105 is greater than 1 (unity rule), where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in 10 CFR Part 30 Appendix B.

10 CFR 30.35(b) requires, in part, that each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in 10 CFR 30.35(d) must either--(1) Submit a decommissioning funding plan as described in 10 CFR 30.35(e); or (2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 10 CFR 30.35(d) using one of the methods described in 10 CFR 30.35(f).

10 CFR 30.35(c)(4) requires any licensee who has submitted an application for license renewal before July 27, 1990, to provide financial assurance for decommissioning in accordance with 10 CFR 30.35(a) and (b). This assurance was required to be submitted by November 24, 1995.

Contrary to the above, the licensee applied for renewal of Byproduct Material License _____ on (date), and the license authorizes possession and use of (quantity) of (nuclide) and is therefore subject to 10 CFR (specify "30.35(a)" or "30.35(b)"); however, as of (date), the licensee did not submit a decommissioning funding plan or otherwise satisfy the requirements for providing financial assurance for decommissioning.

This is a Severity Level _____ violation (Section 6.3).

NOTE: Citations for violations of the Timeliness Rule must be modified to conform to differences in wording among the requirements in 10 CFR 30.36, 40.42, 70.38, and 72.54. Standard Citations for 10 CFR 30.36 are provided below. These citations may be used as a template to formulate citations for violations of 10 CFR 40.42, 70.38, or 72.54.

10 CFR 30.36(d) requires, in part, that licensees provide notification to the NRC in writing within 60 days of any of the following occurrences:

- (1) The license has expired,**
- (2) The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements,**
- (3) No principal activities under the license have been conducted for a period of 24 months, or**
- (4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.**

Contrary to the above, as of (date) , (specify the occurrence from (1) through (4) above, e.g., "the licensee permanently ceased principal activities conducted under Byproduct Material License No. (number)" , and the licensee failed to notify the NRC in writing within 60 days of this occurrence. (Add, if appropriate: Specifically, the licensee did not notify the NRC of this occurrence until (date) .

This is a Severity Level_____violation (Section 6.3).

NOTE: For failure to begin decommissioning when required, use the citation below with the one of the two "Contrary to this requirement" statements that follow the citation.

10 CFR 30.36(d) requires in part that, unless an extension of time has been granted by the Commission pursuant to §30.36(f), in addition to notifying the NRC of any of the following occurrences:

- (1) The license has expired, or**
- (2) The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements, or**
- (3) No principal activities under the license have been conducted for a period of 24 months, or**
- (4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the**

building or outdoor area is unsuitable for release in accordance with NRC requirements,

a licensee shall either: (1) begin decommissioning its site, or any separate building or outdoor area so that the building or outdoor area is suitable for release in accordance with NRC requirements; or (2) if required by §30.36(g)(1), submit, within 12 months of the notification, a decommissioning plan and begin decommissioning upon approval of that plan.

Contrary to the above, the licensee had not been granted an extension of time under §30.36(f) and was not required to submit a decommissioning plan pursuant to §30.36(g)(1), and, as of (date), the licensee notified NRC that [Specify the occurrence from (1) through (4) above, e.g., “The licensee permanently ceased activities conducted under Byproduct Material License No. _____; however, the license failed to begin decommissioning its (site/building/area) containing residual activity, including (specify nuclide(s) and approximate activity). Specifically, the licensee (did not begin) / (had not begun) decommissioning (until) / (as of) (date).]

This is a Severity Level _____ violation (Section 6.3)

or

Contrary to the above, the NRC approved the licensee’s decommissioning plan on (date); however, the licensee (did not begin) / (had not begun) decommissioning (until) / (as of) (date).

This is a Severity Level _____ violation (Section 6.3)

NOTE: For failure to submit a decommissioning plan, use the citation for 10 CFR 30.36(d) provided above, followed by the citation for 10 CFR 30.36(g)(1).

10 CFR 30.36(g)(1) requires that a decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out the decommissioning have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

- (i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;**
- (ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;**
- (iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or**

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

Contrary to the above, as of (date), the licensee, who was not granted an extension of time pursuant to §30.36(f), notified NRC that [Specify the occurrence from (1) through (4) above, e.g., "The licensee permanently ceased activities conducted under Byproduct Material License No. __; however, the license failed to begin decommissioning its (site/building/area) containing residual activity, including (specify nuclide(s) and approximate activity). Specifically, the licensee (did not begin) / (had not begun) decommissioning (until) / (as of) (date).]

This is a Severity Level _____ violation (Section 6.3).

10 CFR 30.36(e)(1) requires that any license who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so by November 24, 1995.

Contrary to the above, the licensee submitted its detailed cost estimate for decommissioning on (date); however, as of (date), the licensee has not provided financial assurance to cover the detailed cost estimate.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 30.36(h) requires, in part, that a licensee complete decommissioning of its site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning, unless the NRC has approved an alternative decommissioning schedule.

Contrary to the above, the licensee initiated decommissioning of its (identify the site, building, or outdoor area) on (date); however, the licensee (did not complete) / (had not completed) the decommissioning (until) / (as of) (date), and the NRC has not approved an alternate decommissioning schedule.

This is a Severity Level _____ violation (Section 6.3).

TRANSFER OF MATERIAL

10 CFR 30.41(a) and (b)(5) require, in part, that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or Agreement State.

Contrary to the above, on (date), the licensee transferred a source containing (amount) curies of (nuclide) to (person), a person who was not authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or Agreement State.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 30.41(c) requires that, prior to transferring byproduct material, the licensee verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. 10 CFR 30.41(d) specifies acceptable methods for this verification.

Contrary to the above, on (date), the licensee transferred (amount) millicuries of (byproduct material) to (transferee) and, prior to the transfer, the licensee did not verify by an acceptable method that the transferee's license authorized receipt of this material.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 30.51(a) requires that each licensee keep records showing the receipt, transfer, and disposal of byproduct material.

Contrary to the above, as of (date), the licensee did not keep records of the (receipt) / (transfer) / (disposal) of (byproduct material). This is a Severity Level _____ violation (Section 6.3).

10 CFR PART 31 GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

10 CFR 31.5(c)(1) requires that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels.

Contrary to the above, as of (date), the licensee did not assure that the label affixed to a (manufacturer, model, name of device) containing (byproduct material) at the time of receipt and bearing a statement that removal of the labels is prohibited, was maintained on the device.

This is a Severity Level _____ violation (Section 6.3).

or

Contrary to the above, as of (date), the licensee did not comply with all instructions and precautions provided by the label affixed to a (manufacturer, model, name of device) containing (nuclide). Specifically, the licensee did not [Specify how the licensee did not comply with the instructions and/or precautions provided by the label].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 31.5(c)(2) requires, with the exception of the devices listed in subparagraphs (i) and (ii), that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six month intervals or at such other intervals as are specified in the label.

Contrary to the above, the licensee did not test (manufacturer, model, name of device containing (nominal activity) (nuclide)), which is not subject to the exemptions specified in subparagraphs (i) and (ii), for (leakage) / (proper operation of the on-off mechanism) / (proper operation of the on-off indicator) between (date) and (date), an interval greater than the interval specified (in the regulation) / (on the label).

This is a Severity Level _____ violation (Section 6.3).

10 CFR 31.5(c)(3) requires that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall assure that tests for leakage of radioactive material and proper operation of the on-off mechanism

and indicator, if any, and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed: (1) in accordance with the instructions provided by the labels; or (2) by a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to perform such activities.

Contrary to the above, on (date) , (specify the testing, installation, servicing, or removal activity) of the licensee's (manufacturer, model, name of device) containing (nuclide) was not performed in accordance with the instructions provided by the labels or by a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to perform such activities. Specifically, [Specify the facts that provide the basis for this violation].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 31.5(c)(4) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall maintain records showing the results of tests for leakage and proper operation of the on-off mechanism and indicator, and of other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment. The records must show the dates of performance of, and the names of the persons performing the recorded event. These records must be retained for three years or until the sealed source is transferred or disposed of.

Contrary to the above, as of (date) , the licensee did not maintain records of (specify the testing, installation, servicing, or removal activity) performed on (date) on the licensee's (manufacturer, model, name of device) containing (specify the byproduct material) for [Specify the appropriate time period, i.e., three years or until the sealed source was transferred or disposed of].

This is a Severity Level _____ violation (Section 6.3).

NOTE: The following regulations may involve application of the "Lost Source Policy" which should be considered in dispositioning cases where devices are abandoned, inappropriately disposed of, or transferred to persons not licensed to receive the device.

10 CFR 31.5(c)(6) requires that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall not abandon the device containing byproduct material.

Contrary to the above, as of (date) , the licensee abandoned a (manufacturer, model, name of device) containing (nuclide) that the licensee possessed pursuant to a general license. Specifically, the device was [Indicate how the device was abandoned].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 31.5(c)(8) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall, except as provided in 10 CFR 31.5(c)(9), transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device.

Contrary to the above, on (date), the licensee (transferred) / (disposed of) a (manufacturer, model, name of device) containing (nuclide). This (transfer) / (disposal) was made to a person who did not hold a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device, and the exception in 10 CFR 31.5(c)(9) did not apply. Specifically, the device was (transferred to) / (disposed of in) (specify who received it) (who was/which was) unlicensed to receive the device.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 31.11(c)(1) requires, in part, that the general licensee shall not possess at any one time, pursuant to the general license in 10 CFR 31.11(a), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, and/or iron-59 in excess of 200 microcuries.

Contrary to the above, on (date), at (location), the licensee possessed (activity) of (nuclide) under the general license, an amount in excess of 200 microcuries permitted under this part.

This is a Severity Level _____ violation (Section 6.3).

10 CFR PART 34 RADIOGRAPHY

NOTE: These requirements apply to persons using sealed sources containing byproduct material in industrial radiography. The provisions in this part are in addition to, and not in substitution for, other requirements of this chapter. These requirements **do not apply to** the medical uses of byproduct material.

10 CFR 34.23(a) requires, in part, that during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

Contrary to the above, on (date), a radiographer, employed by the licensee working at (location), did not secure the sealed source assembly in the shielded position after returning the source to the shielded position.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.25(a) requires, in part, that the licensee keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present to make physical radiation surveys required by 10 CFR parts 20 and 34.

Contrary to the above, on (date), at (location), the licensee did not keep sufficient calibrated and operable radiation survey meters to make the physical radiation surveys required by 10 CFR parts 20 and 34 during radiographic operations in that no operable radiation survey instruments were available at the site.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.25(b)(1) requires, in part, that each survey instrument used to conduct radiation surveys be calibrated at intervals not to exceed six months, and after each instrument servicing.

Contrary to the above, on (date), a licensee radiographer conducted radiation surveys with a (model name and number) survey instrument which was last calibrated on (date), an interval greater than six months.

This is a Severity Level _____ violation (Section 6.3).

or

Contrary to the above, on (date), a licensee radiographer conducted radiation surveys with a (model name and number) survey instrument which was not calibrated after servicing.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.27(c)(1) requires that each sealed source be tested for leakage at intervals not to exceed six months.

Contrary to the above, from (date) to (date), an interval greater than six months, the licensee did not leak test a (amount) curie (nuclide) sealed source.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.27(e) requires that each exposure device using depleted uranium (DU) shielding and an “S” tube configuration must be tested for DU contamination at intervals not to exceed 12 months.

Contrary to the above, from (date) to (date), an interval greater than 12 months, the licensee did not leak test a (model name and number and serial number) exposure device.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.29(a) requires, in part, that the licensee conduct a quarterly physical inventory to account for all sealed sources.

Contrary to the above, from (date) to (date), an interval greater than a calendar quarter, the licensee did not perform a physical inventory of all sealed sources.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.31(a) requires that the licensee perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. If equipment problems are found, the equipment must be removed from service until repaired.

Contrary to the above, on (date), the licensee did not perform a visual and/or operability check(s) to ensure that the equipment listed above, was in good working condition, that the sources were adequately shielded, and that the required labeling was present for a (model name and number) (exposure device, etc.) prior to use that day.

This is a Severity Level _____ violation (Section 6.3).

or

Contrary to the above, on (date), the licensee did not remove a (model name and number) (exposure device, etc.) from service until it was repaired. Specifically,

[describe why meter, device or associated equipment was not functional and should not have been used].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.33(a) requires that each entrance used for personnel access to the high radiation area in a permanent radiographic installation have either an entrance control of the type described in 10 CFR 20.1601(a)(1), or both visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed and the audible signal must be actuated when an attempt is made to enter the installation while the source is exposed.

Contrary to the above, on (date), each entrance used for personnel access to the high radiation area of the licensee's permanent radiographic installation located at (location) did not have the required entrance control or both visible and audible signals (if only one lacking, specify which one) as required.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.41(a) requires, in part, that radiographic operations cannot be performed at a location other than a permanent radiographic installation if only one qualified radiographer is present.

Contrary to the above, on (date), radiographic operations were performed with only one qualified individual present at (location).

This is a Severity Level _____ violation (Section 6.3).

and/or

10 CFR 34.41(a) requires, in part, that whenever radiographic operations are performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has met, at a minimum, the requirements of § 34.43(c).

Contrary to the above, on (date), at (location), a radiographer was not accompanied by a qualified radiographer or an individual who had at a minimum met the requirements of 10 CFR 34.43(c) when [Specify the radiographic operation] was performed. As a result, radiographic operations were performed with only one qualified individual present.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(a) requires that the licensee not permit any individual to act as the additional qualified individual until such individual has met the requirements of § 34.43(g) which includes specified training in addition to a minimum of 2 months of on-the-job

training, and certification by a certifying entity through a radiographer certification program, in accordance with the criteria specified in Appendix A of 10 CFR Part 34.

Contrary to the above, between (date) and (date), the licensee permitted (an) individual(s) to act as the additional qualified individual on (number) occasions before (the or these) individual(s) had received training in the subjects specified in 10 CFR 34.43(g) in addition to a minimum of 2 months of on-the-job training, and (was/were) certified by a certifying entity through a radiographer certification program in accordance with the criteria specified in the Appendix A of 10 CFR part 34.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(b)(1) requires that the licensee not permit any individual to act as a radiographer until such individual has received copies of and instruction in the NRC regulations contained in: 10 CFR part 34; 10 CFR 30.7, 30.9, and 30.10; applicable sections of 10 CFR parts 19 and 20; applicable DOT regulations as referenced in 10 CFR part 71; the NRC license(s) under which the radiographer will perform industrial radiography; and the licensee's operating and emergency procedures.

Contrary to the above, the licensee permitted (an) individual(s) to act as (a) radiographer(s) on (date) at (location) without having first received [specify which copies of and/or instructions from those listed above, were not provided to the individual acting as the radiographer].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(b)(2) requires that the licensee not permit any individual to act as a radiographer until such individual has demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering this material.

Contrary to the above, between (date) and (date), the licensee permitted (an) individual(s) to act as (a) radiographer(s) on (number) occasions when (the/these) individual(s) had not demonstrated understanding of the instructions specified above by the successful completion of a written or oral examination covering this material.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(b)(3) requires that the licensee not permit any individual to act as a radiographer until such individual has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments.

Contrary to the above, between (date) and (date), the licensee permitted (an) individual(s) to act as (a) radiographer(s) on (number) occasions when (the) / (these) individual(s) had not received training in the use of the licensee's radiographic exposure

devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(b)(4) requires that the licensee not permit any individual to act as a radiographer until such individual has demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment, described in 10 CFR 34.43(b)(1) and (b)(2), by successful completion of a practical examination covering this material.

Contrary to the above, between (date) and (date), the licensee permitted (an) individual(s) to act as (a) radiographer(s) on (number) occasions when (the) / (these) individual(s) had not demonstrated understanding of the instructions specified above by the successful completion of a practical examination covering this material.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(c)(1) requires that the licensee not permit any individual to act as a radiographer's assistant until such individual has received copies of and instruction in NRC regulations contained in: 10 CFR part 34; 10 CFR 30.7, 30.9, and 30.10; the applicable sections of 10 CFR parts 19 and 20; applicable DOT regulations as referenced in 10 CFR part 71; the NRC license(s) under which the radiographer's assistant will perform industrial radiography; and the licensee's operating and emergency procedures.

Contrary to the above, between (date) and (date), the licensee permitted (an) individual(s) to act as (a) radiographer's assistant(s) on (number) occasions without having first received [Specify which copies of and/or instructions from those listed above, were not provided to the individual acting as the radiographer's assistant].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(c)(2) requires that the licensee not permit any individual to act as a radiographer's assistant until such individual has demonstrated competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use.

Contrary to the above, between (date) and (date), the licensee permitted (an) individual(s) to act as (a) radiographer's assistant(s) on (number) occasions when (the/these) individual(s) had not demonstrated competence to use, under the personal supervision of the radiographer, the (specify the device(s), sealed source(s) or instrument(s) from those listed above) that the assistant will use.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(c)(3) requires that the licensee not permit any individual to act as a radiographer's assistant until such individual has demonstrated understanding of the instructions in § 34.43(c)(1) by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in § 34.43(c)(2) by successfully completing a practical examination on the use of such hardware.

Contrary to the above, between (date) and (date), the licensee permitted (an) individual(s) to act as (a) radiographer's assistant(s) on (number) occasions when (the/these) individual(s) had not demonstrated understanding of the instructions specified above by the successful completion of a written test.

This is a Severity Level _____ violation (Section 6.3).

and/or

Contrary to the above, between (date) and (date), the licensee permitted (an) individual(s) to act as (a) radiographer's assistant(s) on (number) occasions when (the/these) individual(s) had not demonstrated competence in the use of the hardware specified above by successfully completing a practical examination on the use of such hardware.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(e)(1) requires, in part, that the RSO or designee shall conduct an inspection program that includes the observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed six months.

License Condition__incorporates the inspection program required by 10 CFR 34.13(e) as submitted in licensee's application dated (date), into License No.____.

Contrary to the above, as of (date), the licensee had not observed the performance of a (radiographer/radiographer's assistant) involved in radiographic operations since (date), an interval in excess of six months.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.43(f) requires the licensee to maintain records of training of radiographers and radiographer's assistants, including certification documents, written and practical examinations, refresher training, and inspections of job performance, for 3 years after the date the record is made in accordance with § 34.79.

Contrary to the above, between (date) and (date), at (location), the licensee did not maintain records of training of radiographers and/or radiographer's assistants, including copies of written and practical examinations, refresher training, and inspections of job performance, for the required period.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.46 requires that whenever a radiographer's assistant uses radiographic exposure devices, associated equipment, or sealed sources, or conducts radiation surveys required by § 34.49(b) to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision must include: (1) the radiographer's physical presence at the site where the sealed sources are being used; (2) the availability of the radiographer to give immediate assistance if required; and, (3) the radiographer's direct observation of the assistant's performance of the above referenced operations.

Contrary to the above, on (date), at (location), a licensee radiographer's assistant operated radiographic exposure devices and conducted radiation surveys without the personal supervision of a radiographer in that [Specify the deficiency of the supervision].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.47(a) requires that the licensee not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm rate meter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.

Contrary to the above, on (date), at (location), a (radiographer/ radiographer's assistant) employed by the licensee, did not wear a (specify the equipment from those listed above), while conducting radiographic operations.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.47(b) requires that direct reading dosimeters be read and the exposures recorded at the beginning and end of each shift, and that the licensee retain each record of these exposures for 3 years after the record is made in accordance with § 34.83.

Contrary to the above, from (date) to (date), radiographers employed by the licensee did not record their direct reading dosimeter exposures.

This is a Severity Level _____ violation (Section 6.3).

or

Contrary to the above, the licensee did not retain each record of these exposures for the required period.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.47(c) requires that pocket dosimeters or electronic personal dosimeters be checked at intervals not to exceed twelve months for correct response to radiation, and must read within plus or minus 20 percent of the true radiation exposure.

Contrary to the above, from (date) to (date), an interval exceeding twelve months, pocket dosimeters were not checked for correct response to radiation or, when checked, did not read within plus or minus 20 percent of the true radiation exposure.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.47(d) requires that if an individual's pocket chamber is found to be off- scale or if his/her electronic personal dosimeter reads greater than 2 millisieverts (200 mrem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personal dosimeter must be sent for processing within 24 hours.

Contrary to the above, on (date) during radiographic operations performed at (location) a (radiographer's /radiographer assistant's) pocket dosimeter was found to be off-scale or read greater than 200 mrem, and the (film badge/TLD) worn by the individual (was/were) not sent for processing within 24 hours.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.49(b) requires, in part, that the licensee survey the radiographic exposure device and the guide tube with a calibrated and operable radiation survey instrument after each radiographic exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position.

Contrary to the above, on (date), a radiographer, employed by the licensee, did not perform a survey after a radiographic exposure to determine that the sealed source had been returned to its shielded position.

This is a Severity Level _____ violation (Section 6.3).

or

Contrary to the above, on (date), at (location), a radiographer, employed by the licensee, did not survey the radiographic exposure device or the guide tube to determine that the sealed source had been returned to its shielded position.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.51 requires that during each radiographic operation, the additional radiographer or other individual present, as required by § 34.41, shall maintain

continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in 10 CFR part 20, except at permanent radiographic installations where all entryways are locked and the requirements of § 34.33 are met.

Contrary to the above, on (date), at a temporary jobsite in (location), neither the additional radiographer, nor any other qualified individual present during radiographic operations, maintained continuous direct visual surveillance of the radiographic operation to protect against entry into the high radiation area. Specifically, [Briefly provide the details].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.53 requires, that all areas in which industrial radiography is being performed be conspicuously posted as required by 10 CFR 20.1902(a) and (b).

Contrary to the above, on (date), during radiographic operations performed at (location), the licensee did not post the radiation area and the high radiation area in which industrial radiography was being performed.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.67 requires that each licensee shall maintain records for 3 years of leak tests for sealed sources and devices containing DU.

Contrary to the above, from (date) to (date), the licensee did not maintain the records of leak tests for sealed sources and devices containing DU for the required period.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.71 requires, in part, that each licensee maintain utilization logs, which shall be kept available for 3 years after the log is made, showing for each sealed source: (1) a description including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source is located; (2) the identity and signature of the radiographer to whom assigned; and, (3) the plant or site where used and dates of use, including the dates removed and returned to storage.

Contrary to the above, on (date), the licensee did not maintain utilization logs at its facility located in (location), for radiographic operations conducted between (date) and (date), at (location(s)).

This is a Severity Level _____ violation (Section 6.3).

or

Contrary to the above, as of (date), the licensee's utilization logs were inadequate because the logs did not show for each sealed source: [Indicate the deficiencies].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 34.85 requires, in part, that each licensee must maintain for 3 years a record of each exposure device survey conducted before the device is placed in storage as specified in § 34.49(c), if that survey is the last one performed in the workday.

Contrary to the above, as of (date), the licensee did not retain records of the last survey conducted before the device was placed into storage, and the survey was the last one performed in the work day.

This is a Severity Level _____ violation (Section 6.3).

10 CFR PART 35 MEDICAL USE

10 CFR 35.24(a) requires the licensee's management to approve in writing:

- (1) Requests for license applications, renewals, or amendments before submittal to the Commission;
- (2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and,
- (3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26.

Contrary to the above, from (date) to (date), the licensee's management did not approve, in writing, [Select from 1-3 above.]

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.24(b) requires that a licensee's management appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

Contrary to the above, between (date) and (date), the licensee's management failed to appoint a Radiation Safety Officer, who agreed, in writing, to be responsible for implementing the radiation protection program.

This is a Severity Level _____ violation (Section 6.3).

or

Contrary to the above, on (date), the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the licensee's procedures (regulatory requirements). Specifically, [Describe how the licensee violated the procedure or regulatory requirement.]

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.24(f) requires, in part, that the membership of the Radiation Safety Committee include an authorized user of each type of use permitted by the license, a Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer.

Contrary to the above, as of (date), the membership of the licensee's Radiation Safety Committee did not include [Select the group member that was not represented].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.24(g) requires the licensee to provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to (1) Identify radiation safety problems; (2) Initiate, recommend, or provide corrective actions; (3) Stop unsafe operations; and, (4) Verify implementation of corrective actions.

Contrary to the above, the licensee did not provide the Radiation Safety Officer sufficient authority (organizational freedom/time/resources/management prerogative) to identify radiation safety problems (initiate, recommend, or provide corrective actions/stop unsafe operations/verify implementation of corrective actions), in that, on (date), [Describe the issue].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.24(h) requires the licensee to retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

Contrary to the above, from (date) to (date) the licensee failed to maintain records of [Describe the actions for which there were no records].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.27(a)(1) requires, in part, a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user to instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material;

Contrary to the above, as of (date), the licensee did not instruct [Identify the supervised individual, e.g., "a nuclear medicine technologist"] in the licensee's written radiation protection procedures (written directive procedures/regulations of this chapter/license conditions with respect to the use of byproduct material).

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.27(a)(2) requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user to require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

Contrary to the above, as of (date), the licensee did not require [Identify the supervised individual, e.g., "a nuclear medicine technologist"] to follow the instructions of the supervising authorized user for medical uses of byproduct material (written radiation protection procedures established by the licensee/written directive procedures/regulations of this chapter/license conditions with respect to the medical use of byproduct material).

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.27(b)(1) requires, in part, a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, to instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material.

Contrary to the above, as of (date), the licensee did not instruct [Identify the position of the supervised individual, e.g., "a pharmacy technologist"] in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material;

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.27(b)(2) requires supervised individuals to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

Contrary to the above, on (date), a [Identify the position of the supervised individual, e.g., technologist], an individual under the supervision of the licensee's authorized user (authorized nuclear pharmacist), [Describe how the individual failed to follow the instruction while using byproduct material. Note: Specify the byproduct material].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) The patient's or human research subject's identity is verified before each administration; and (2) Each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

Contrary to the above, the licensee did not develop (implement and/or maintain) written procedures to provide high confidence that [Select from 1 and/or 2 above].

This is a Severity Level _____ violation (Section 6.3)

and/or

Contrary to the above, the licensee's procedures did not meet the requirements described in § 35.41(b), in that the procedures did not require [Insert the item(s) from § 35.41(b) that apply].

This is a Severity Level _____ violation (Section 6.3)

10 CFR 35.41(c) requires the licensee to retain a copy of the procedures required under 10 CFR 35.41(a) in accordance with § 35.2041.

Contrary to the above, the licensee did not retain a copy of the procedure(s) for [Describe the procedure(s)], dated (date), which, in accordance with § 35.2401, is (are) required under 10 CFR 35.41(a).

This is a Severity Level _____ violation (Section 6.3)

10 CFR 35.60(a) requires a licensee, who performs direct measurements in accordance with § 35.63, to possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

Contrary to the above, from (date) to (date), the licensee did not possess and use instrumentation to measure the activity of unsealed byproduct material before it was administered to each patient or human research subject.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.60(b) requires licensees to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, from (date) to (date), the licensee did not calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.60(c) requires the licensee to retain a record of each instrument calibration required by this section in accordance with § 35.2060.

Contrary to the above, the licensee did not retain a copy of the calibration record for [Describe the instrument] calibrated on (date), as required by this section in accordance with § 35.2060.

This is a Severity Level _____ violation (Section 6.3)

10 CFR 35.61(a) requires, in part, that a licensee calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration.

Contrary to the above, as of (date), the licensee was using a (manufacturer name and model number) survey instrument to show compliance with this part and 10 CFR Part 20, and this survey instrument had not been calibrated from (date) through (date).

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.63(a) requires that a licensee determine and record the activity of each dosage before medical use.

Contrary to the above, on (date), the licensee did not determine and record the activity of a radiopharmaceutical containing (microcuries)/(millicuries) of (byproduct material), before it was administered to a patient (human research subject) for medical use.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.63(b) requires that, for a unit dosage, the license must determine the activity either by (1) direct measurement of radioactivity; or (2) a decay correction, based on the activity or activity concentration determined by (i) A manufacturer or preparer licensed under §32.72 of this chapter or equivalent Agreement State requirements; or (ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

Contrary to the above, on (date), the licensee did not determine the activity in a unit radiopharmaceutical dosage containing (byproduct material), before it was administered to a patient (human research subject) for medical use. Specifically, [Describe what occurred].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.63(c) requires that, for other than a unit dosage, the license must determine the activity either by (1) direct measurement of radioactivity; (2) a combination of measurement of radioactivity and mathematical calculations; or (3) a combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements.

Contrary to the above, on (date), the licensee did not determine the activity in a radiopharmaceutical dosage containing (byproduct material), before it was administered to a patient (human research subject) for medical use.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.615(a) requires licensees to control access to treatment rooms containing remote afterloader units, teletherapy units, and/or gamma stereotactic radiosurgery units, by a door at each entrance.

Contrary to the above, from (date) to (date), access to the (remote afterloader units, teletherapy units, and/or gamma stereotactic radiosurgery units) treatment room was not controlled by a door at each entrance.

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.615(b) requires licensees to equip each entrance to treatment rooms containing remote afterloader units, teletherapy units, and/or gamma stereotactic radiosurgery units, with an electrical interlock system that will: (1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed; (2) Cause the source(s) to be shielded when an entrance door is opened; and (3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

Contrary to the above, as of (date), the licensee did not equip the entrance to the remote afterloader units (teletherapy units and/or gamma stereotactic radiosurgery units) treatment room with an electrical interlock system that will [Select from 1-3 above].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.3045(a) requires licensees to report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in –

- (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and**
 - (i) The total dose delivered differs from the prescribed dose by 20 percent or more;**
 - (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or**
 - (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.**
- (2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following –**

- (i) An administration of a wrong radioactive drug containing byproduct material;
 - (ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;
 - (iii) An administration of a dose or dosage to the wrong individual or human research subject;
 - (iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or
 - (v) A leaking sealed source.
- (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

Contrary to the above, on (date), the licensee became aware that a medical event had occurred, and the licensee did not notify the NRC. Specifically, the administration of byproduct material (radiation from byproduct material) resulted in [Provide a brief description of the medical event to demonstrate that it meets the applicable definition used above].

This is a Severity Level _____ violation (Section 6.3).

10 CFR 35.3045(c) requires the licensee to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event.

Contrary to the above, on (date), the licensee became aware that a medical event had occurred, and the licensee did not notify the NRC until (date), which was later than the next calendar day. Specifically, the administration of byproduct material (radiation from byproduct material) resulted in [Provide a brief description of the medical event to show that it meets the applicable definition used above].

This is a Severity Level _____ violation (Section 6.3).

10 CFR PART 71 PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

10 CFR 71.3 states that, except as authorized in a general license or a specific license issued by the Commission, or as exempted by other paragraphs in 10 CFR Part 71, no licensee may: (1) deliver licensed material to a carrier for transport, or (2) transport licensed material.

10 CFR 71.14(b) states, in part, that a licensee is exempt from all requirements of 10 CFR Part 71, other than 10 CFR 71.5 and 10 CFR 71.88, with respect to shipment or carriage of a package containing no more than a Type A quantity of radioactive material, provided the package contains no fissile material or if the fissile material exemption standards of 10 CFR 71.15 are satisfied.

Contrary to the above, on (date) , the licensee (transported) / (delivered to a carrier for transport) (amount) of (nuclide) , which is greater than a Type A quantity of radioactive material; and the licensee was not otherwise exempted pursuant to 10 CFR Part 71, nor did the licensee meet the criteria for a general license, nor was this transport authorized in a specific license issued by the Commission.

This is a Severity Level _____ violation (Section 6.8).

Contrary to the above, on (date) , the licensee (transported) / (delivered to a carrier for transport) (amount) grams of fissile material consisting of (nuclide(s)) , which does not meet the exemption standards set forth in 10 CFR 71.15; and the licensee was not otherwise exempted pursuant to 10 CFR Part 71, nor did the licensee meet the criteria for a general license, nor was this transport authorized in a specific license issued by the Commission.

This is a Severity Level _____ violation (Section 6.8).

CITATIONS FOR FAILURE TO FOLLOW DOT REGULATIONS

NOTE: Citations for failure to follow specific DOT regulations should include, in the first paragraph, the authority under 10 CFR 71.5(a). Use the paragraph below. Then list the specific citations as subheadings, without repeating the initial paragraph.

10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397.

10 CFR 71.17 states, in part, that a general license to transport licensed material, or to deliver licensed material to a carrier for transport, applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of 10 CFR Part 71; has a copy of the certificate of compliance, or other approval of the package; and submits in writing to NRC, prior to the first use of the transport package, the licensee's name, license number, and package identification number specified in the package approval.

Contrary to the above, as of (date) , the licensee routinely (transported licensed material) / (delivered licensed material to a carrier for transport) under the general license pursuant to 10 CFR 71.17, and the licensee (did not have a quality assurance program approved by the Commission) / (did not have a copy of the certificate of compliance, or other approval of the package) / (had not submitted in writing to NRC prior to the first use of the transport package the licensee's name, license number, and package identification number).

This is a Severity Level _____ violation (Section 6.8).

10 CFR PART 150 EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

RECIPROCITY

10 CFR 150.20(a) provides, in part, that any person who holds a specific license from an Agreement State is granted an NRC general license to conduct the same activity in non-Agreement States, areas of exclusive Federal jurisdiction within Agreement States, and in offshore waters, provided that the provisions of 10 CFR 150.20(b) have been met.

10 CFR 150.20(b)(1) requires, in part, that any person engaging in activities in non-Agreement States, areas of exclusive Federal jurisdiction within Agreement States, and in offshore waters, shall, at least 3 days before engaging in each such activity, file 4 copies of NRC Form-241, "Report of Proposed Activities in Non- Agreement States," with the Regional Administrator of the appropriate NRC regional office.

Contrary to the above, on (date), (name of Agreement State Licensee), a licensee of (Agreement State), used (nuclide) in [Specify location, including State], a non-Agreement State (area of exclusive Federal jurisdiction within Agreement State/offshore waters), without filing Form-241 with the NRC.

This is a Severity Level _____ violation (Section 6.3).

49 CFR PART 172 HAZARDOUS MATERIALS

SHIPPING PAPERS

NOTE: If there is no shipping paper, choose one of the two citations below, depending on whether the licensee transported the material or offered it for transport. If the shipping paper is incomplete or inaccurate, begin with either of the following two citations, as appropriate, followed by the citations addressing emergency response information; specific citations, choosing from among the citations addressing the requirements contained in Subpart G of 49 CFR Part 172.

49 CFR 172.200(a) requires, with exceptions not applicable here, that each person who offers a hazardous material for transportation shall describe the hazardous material on the shipping paper in the manner required by subpart C of 49 CFR Part 172.

Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on (date), the licensee offered (licensed material) to a carrier for transport and did not include with the shipment a shipping paper describing the material.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 177.817(a) requires that a carrier cannot accept hazardous material for transportation or transport unless it is accompanied by shipping papers prepared in accordance with 49 CFR 172.200-203. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on (date), the licensee transported (licensed material) outside the confines of its plant without a shipping paper.

This is a Severity Level _____ violation (Section 6.8).

EMERGENCY RESPONSE TELEPHONE NUMBER

NOTE: If the emergency response telephone number is on the shipping paper but does not meet the requirements of 49 CFR 172.602, use 49 CFR 172.604.

49 CFR 172.201(d) requires that a shipping paper contain an emergency response telephone number, as prescribed in subpart G of 49 CFR Part 172.

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the shipping paper that accompanied the shipment did not contain an emergency response telephone number.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.202(a) and (b) require in part, with exceptions not applicable here, that the shipping description of a hazardous material on the shipping paper include, in the following sequence: (1) the proper shipping name prescribed for the material in 172.101 (2) the hazard class prescribed for the material as shown in Column 3 of the 172.101 Table, and (3) the identification number prescribed for the material as shown in Column 4 of the 172.101 Table. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the shipping description on the shipping paper that accompanied the shipment did not include (select the missing item(s) from the paragraph above).

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.203(c)(2) requires that the letters "RQ" be entered on the shipping paper either before or after the basic description required for each hazardous substance. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the letters "RQ" were not entered either before or after the description on the shipping paper that accompanied the shipment.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.203(d) requires, in part, that the description for a shipment of radioactive material include: (1) the name or abbreviation (e.g., ⁹⁹Mo) of each radionuclide that is in the radioactive material and is listed in 49 CFR 173.435, or for mixtures of radionuclides, those nuclides determined in accordance with the provisions of 49 CFR 173.433(f); (2) the physical and chemical form of the material (if not special form); (3) the activity contained in each package of the shipment in terms of the appropriate SI units (e.g., Becquerel, Terabecquerel etc...), or in terms of appropriate SI units followed by customary units (e.g., curies, millicuries, or microcuries) [Note that for domestic transportation, use of customary units only is authorized until April 1, 1997]; (4) the category of label applied to each package (e.g., RADIOACTIVE WHITE-I), and 5) the transport index assigned to each package in the shipment bearing RADIOACTIVE YELLOW-II OR YELLOW-III labels.

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the description on the shipping paper that accompanied the shipment did not include (select missing item(s) from above).

This is a Severity Level _____ violation (Section 6.8).

or

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the description on the shipping paper that accompanied the shipment did not include the correct (select item(s) from above). Specifically, (state how each item was incorrect).

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.310 requires, in part, that for each package containing radioactive materials, the packaging must be marked on the outside of the package, in letters at least 13 mm (0.5 inch) high, with the words "TYPE A" or "TYPE B" as appropriate.

Contrary to the above, as of (date) , the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material) in a (Type A) / (Type B) package which was not marked "(Type A)" / "(Type B)".

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.312 requires in part, with exceptions not applicable here, that each package having an inside packaging containing liquid hazardous materials be (1) packed with closures upward, and (2) legibly marked, with package orientation markings that conform pictorially to ISO Standard 780-1985, on two opposite vertical sides of the package with the arrows pointing in the correct upright direction.

Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material) in liquid form, and the outer package was not marked on two opposite vertical sides with package orientation arrows pointing in the correct upright direction.

This is a Severity Level_____violation (Section 6.8).

49 CFR 172.403 requires, in part, with exceptions not applicable here, that each package of radioactive material be labeled, as appropriate, with two RADIOACTIVE WHITE-I, RADIOACTIVE YELLOW-II, or RADIOACTIVE YELLOW-III labels on opposite sides of the package. The contents, activity, and transport index must be entered in the blank spaces on the label using a legible and durable, weather resistant means. The contents entered on the label must include the name or abbreviation (e.g., ⁹⁹Mo) of the radionuclides as taken from the listing in 49 CFR 173.435, or for mixtures of radionuclides, those nuclides determined in accordance with the provisions of 49 CFR 173.433(f), with consideration of space available on the label. The activity must be expressed in terms of the appropriate SI units (e.g., Becquerel, Terabecquerel etc...), or in terms of appropriate SI units followed by customary units (e.g., curies, millicuries, or microcuries) [Note that for domestic transportation, use of customary units only is authorized until April 1, 1997].

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material) without the required (RADIOACTIVE WHITE-I) / (RADIOACTIVE YELLOW-II) / (RADIOACTIVE YELLOW-III) labels.

This is a Severity Level_____violation (Section 6.8).

or

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the RADIOACTIVE label affixed to the package did not identify the (contents) / (activity) / (transport index).

This is a Severity Level_____violation (Section 6.8).

or

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the RADIOACTIVE label affixed to the package incorrectly identified the (contents) / (activity) / (transport index). Specifically, (state how each item was incorrect).

This is a Severity Level_____violation (Section 6.8).

or

Contrary to the above, on (date) , the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material) , and the package had only one RADIOACTIVE label affixed to it.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.403(b) requires that the label to be affixed to a package is based on the radiation level at the surface of the package and the transport index. The label to be applied must be the highest category required for either of the two determining conditions of the package. 49 CFR 172.403(c) defines the categories of labels to be applied to radioactive materials packages and requires, in part, that: (1) packages with surface radiation levels of less than or equal to 0.005 millisievert per hour (0.5 millirem per hour) be labeled "White-I," (2) packages with surface radiation levels greater than 0.005 millisievert per hour (0.5 millirem per hour) but less than or equal to 0.5 millisievert per hour (50 millirem per hour) be labeled "Yellow-II," and (3) packages with surface radiation levels greater than 0.5 millisievert per hour (50 millirem per hour) be labeled "Yellow-III."

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material) in a package that was improperly labeled. Specifically, the package had surface radiation levels of (specify) millirem per hour and was labeled (____), instead of (____).

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.403(b) requires that the label to be affixed to a package is based on the radiation level at the surface of the package and the transport index (T.I.). The label to be applied must be the highest category required for either of the two determining conditions of the package. 49 CFR 172.403(c) defines the categories of labels to be applied to radioactive materials packages and requires, in part, that: (1) packages with a T.I. of zero (i.e., a measured T.I. of not greater than 0.05) be labeled "White-I", packages with a T.I. of more than zero but less than or equal to 1.0 be labeled "Yellow-II," and (2) packages with a T.I. greater than 1.0 be labeled "Yellow-III."

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material) in a package that was improperly labeled. Specifically, the package had a T.I. of (specify) and was labeled , instead of _____.

This is a Severity Level _____ violation (Section 6.8).

PROHIBITED PLACARDING

NOTE: DOT regulations prohibit the use of the "RADIOACTIVE" placard ONLY when the vehicle contains NO radioactive material. The violation below normally should be considered to be a minor violation and not the subject of formal enforcement action in accordance with the Enforcement Policy.

49 CFR 172.502(a) requires, in part, with exceptions not applicable here, that no person affix or display on a transport vehicle any placard unless the placard represents a hazard of the material being transported.

Contrary to the above, on (date), the licensee operated a transport vehicle, outside the site of usage, as specified on the NRC license, or on a public highway, with a "RADIOACTIVE" placard displayed on it and no packages containing radioactive material were present in the vehicle at the time.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.504 prescribes requirements for placarding vehicles used to transport hazardous materials. Specifically, Table 1 requires that the transport vehicle be placarded on each side and each end with a "RADIOACTIVE" placard when transporting: a) packages bearing a "RADIOACTIVE YELLOW-III" label, and b) exclusive-use shipments of low specific activity (LSA) radioactive materials and surface contaminated objects (SCO) transported in accordance with 49 CFR 173.427(b)(3) or (c) (see footnote in Table 1, 49 CFR 173.504(e)).

Contrary to the above, on (date), the licensee transported (licensed material), outside the site of usage, as specified on the NRC license, or on a public highway, in a package with YELLOW-III labels, and the transport vehicle was not placarded with "RADIOACTIVE" placards.

This is a Severity Level _____ violation (Section 6.8).

or

Contrary to the above, on (date), the licensee transported (LSA material/ SCO) consisting of (specify) as an exclusive use shipment in accordance with 49 CFR 173.427(b)(3) or (c), outside the site of usage, as specified on the NRC license, or on a public highway, and the transport vehicle was not placarded with "RADIOACTIVE" placards.

This is a Severity Level _____ violation (Section 6.8).

EMERGENCY RESPONSE TELEPHONE NUMBER

49 CFR 172.600 requires, with exceptions not applicable here, that no person may offer for transportation, accept for transportation, transfer, store, or otherwise handle during transportation, a hazardous material unless emergency response information conforming to Subpart G of 49 CFR Part 172 is immediately available for use at all times the hazardous material is present. 49 CFR 172.602 requires, in part, that the emergency response information must be presented: (1) on a shipping paper; (2) in a document, other than a shipping paper (e.g., a material safety data sheet); or (3) in a separate document (e.g., an emergency response guidance document), in a manner that cross-references the description of the hazardous material on the shipping paper with the emergency response information on the document. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), without the required emergency response information.

This is a Severity Level _____ violation (Section 6.8).

NOTE: If the emergency response telephone number is not entered on the shipping paper, use 49 CFR 172.201(d).

49 CFR 172.602 requires, in part, that as a minimum, the emergency response information required by Subpart G of 49 CFR Part 172 must contain: (1) the basic description and technical name of the hazardous material, (2) immediate hazards to health, (3) risks of fire or explosion, (4) immediate precautions to be taken in the event of an accident or incident, (5) immediate methods for handling fires, (6) initial methods for handling spills or leaks in the absence of fire, and (7) preliminary first aid measures. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the emergency response information that accompanied the shipment did not include (select missing item(s) from above).

This is a Severity Level _____ violation (Section 6.8).

or

Contrary to the above, on (date), the licensee (transported outside the confines of its plant) / (delivered to a carrier for transport) (licensed material), and the emergency response information that accompanied the shipment did not include the

(correct/complete) (select item(s) from above). Specifically, (state how each item was incorrect/incomplete).

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.602(c) requires, with exceptions not applicable here, that the emergency response information specified in 49 CFR 172.602(a) must be maintained by each carrier who transports hazardous material in the same manner as prescribed for shipping papers. 49 CFR 177.817(e) requires, in part, that the driver of a motor vehicle containing hazardous material ensure that the shipping paper is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, (i) when the driver is at the vehicle's controls, the shipping paper shall be: (a) within his immediate reach while he is restrained by the lap belt; and (b) either readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle; (ii) when the driver is not at the vehicle's controls, the shipping paper shall be: (a) in a holder which is mounted to the side of the door on the driver's side of the vehicle; or (b) on the driver's seat in the vehicle. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

Contrary to the above, on (date), the licensee transported (licensed material), outside the site of usage, as specified on the NRC license, or on a public highway, and the driver of the vehicle did not ensure that the emergency response information was readily available in the driver's compartment, as required. Specifically, (state where the emergency response information was and why it was not accessible).

This is a Severity Level _____ violation (Section 6.8).

NOTE: If the emergency response telephone number is not entered on the shipping paper, use 10 CFR 172.201(d).

49 CFR 172.604 requires, in part, that a person who offers a hazardous material for transportation provide a 24 hour emergency response telephone number for use in the event of an emergency involving the hazardous material. The telephone number must be: (1) monitored at all times the hazardous material is in transportation, including storage incidental to transportation, (2) the number of a person who is either knowledgeable of the hazardous material being shipped and has comprehensive emergency response and incident mitigation information for that material, or has immediate access to a person who possesses such knowledge, and entered on the shipping paper.

Contrary to the above, on (date), the licensee delivered to a carrier for transport (licensed material) and the emergency response telephone number on the shipping paper that the licensee used to accompany the shipment was inadequate in that it was not (select from item (1) or (2) above).

This is a Severity Level _____ violation (Section 6.8).

HAZMAT TRAINING REQUIREMENTS

NOTE: Always include the first paragraph below. If there is no hazmat training provided, cite against that paragraph. If the training is incomplete, also include the second citation. Or, if the training records are not adequate, also include the third citation.

49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee performs any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172. The terms Hazmat Employer and Hazmat Employee are defined in 49 CFR 171.8.

Contrary to the above, during the period between (date) and (date), the licensee did not provide training for its hazmat employees as required by Subpart H to 49 CFR Part 172, and the licensee otherwise meets the definition of hazmat employer in 49 CFR 171.8.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.704(a) specifies the elements of hazmat employee training as: (1) general awareness/familiarization training, (2) function-specific training, (3) safety training, (4) security awareness training, and (5) in-depth security training. 49 CFR 172.704(c) requires, in part, that a hazmat employee receive initial training, and recurrent training at least once every three years. For in-depth security training, a hazmat employee must be trained at least once every three years or, if the security plan for which training is required is revised during the three-year recurrent training cycle, within 90 days of implementation of the revised plan.

Contrary to the above, the licensee's did not provide training for its hazmat employees which satisfied the requirements in Subpart H to 49 CFR Part 172, in that [Specify the deficiencies in the training program], and the licensee otherwise meets the definition of hazmat employer in 49 CFR 171.8.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 172.704(d) requires that a record of current training, inclusive of the preceding two years, in accordance with Subpart H of 49 CFR Part 172, shall be created and retained by each hazmat employer for each hazmat employee for as long as that employee is employed by that employer as a hazmat employee and for 90 days thereafter. The record must include: (1) the hazmat employee's name, (2) the most recent

training completion date of the hazmat employee's training, (3) a description, copy, or location of the training materials, (4) the name and address of the person providing the training, and (5) certification that the hazmat employee has been trained and tested in accordance with Subpart H of 49 CFR Part 172.

Contrary to the above, the licensee's records of hazmat employee training were inadequate in that they did not include (Specify the missing/incomplete items from the above list), and the licensee otherwise meets the definition of hazmat employer in 49 CFR 171.8.

This is a Severity Level _____ violation (Section 6.8).

49 CFR PART 173 SHIPPERS: REQUIREMENTS FOR SHIPMENTS AND PACKAGING

49 CFR 173.25 requires, in part, for packages containing hazardous materials and offered for transportation in an overpack, that: 1) the overpack be marked with the proper shipping name and identification number, and labeled as required by 49 CFR Parts 171-177 for each hazardous material contained therein unless markings and labels representative of each hazardous material in the overpack are visible; and 2) the overpack be marked with a statement indicating that the inside (inner) packages comply with prescribed specifications when specification PACKAGING are required, unless specification markings on the inside packages are visible. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, as of (date), the licensee offered for transportation in an overpack (licensed material) that was not marked with the proper shipping name and identification number, nor with any statement indicating that the inner package complied with the prescribed specifications; and the markings on the inside package were not visible.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.411(c) requires that, except for Industrial Packaging Type 1 (IP-1) PACKAGING, each offeror of an industrial package must maintain on file for at least one year after the latest shipment, complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification.

Contrary to the above, as of (date), the licensee shipped (licensed material) in an (IP-2/IP-3) package, and did not maintain for a period of at least one year following that shipment documentation of tests and an engineering evaluation or comparative data showing that the package complied with the applicable specification.

This is a Severity Level _____ violation (Section 6.8).

Contrary to the above, as of (date), the licensee shipped (licensed material) in an (IP-2/IP-3) package, and did not maintain for a period of at least one year following that shipment complete documentation of tests and an engineering evaluation or comparative data showing that the package complied with the applicable specification. Specifically, the documentation was incomplete in that [State how/why the documentation was not adequate, e.g., it did not show that the (construction methods) / (packaging design) / (materials of construction) comply with (the applicable specification)].

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.415(a) requires that each shipper of a DOT Specification 7A Type A package must maintain on file for at least one year after the latest shipment a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with the specification as described in 49 CFR 178.350.

Contrary to the above, as of (date), the licensee shipped (licensed material) in a package marked DOT Specification 7A Type A and did not maintain for a period of at least one year following that shipment documentation of tests and an engineering evaluation or comparative data showing that the package complied with the applicable DOT specification.

This is a Severity Level _____ violation (Section 6.8).

Contrary to the above, as of (date), the licensee shipped (licensed material) in a package marked DOT Specification 7A Type A and did not maintain for a period of at least one year following that shipment complete documentation of tests and an engineering evaluation or comparative data showing that the package complied with the applicable DOT specification. Specifically, the documentation was incomplete in that [State how/why the documentation was not adequate, e.g., it did not show that the (construction methods) / (packaging design) / (materials of construction) comply with (the applicable DOT specification)].

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.421 excepts limited quantities of radioactive material, specified as radioactive material whose activity per package does not exceed the limits in 49 CFR 173.425 and its packaging, from the specification marking, and labeling requirements (except the UN identification number marking described in § 173.422(a), and if not a hazardous substance or hazardous waste, the shipping paper and certification requirements of 49 CFR Parts 171-177, and the requirements of Subpart I of 49 CFR Part 173, provided, among other things, that (Insert here the applicable item(s) from the below list).

- (1) each package meets the general design requirements in 49 CFR 173.410.
- (2) the radiation level at any point on any external surface of the package does not exceed 0.005 millisievert per hour (0.5 millirem per hour)
- (3) the nonfixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a)
- (4) the outside of the inner packaging, or if there is no inner packaging, the outside of the packaging itself bears the marking "Radioactive."
- (5) with exceptions not applicable here, the package does not contain more than 15 grams of uranium-235.
- (6) the material is otherwise prepared for shipment in accordance with 49 CFR 173.422. 49 CFR 173.422 requires, in part, that a limited quantity of radioactive material, prepared for shipment in accordance with 49 CFR 173.421, must, be certified as being acceptable for transportation by having a notice enclosed in or

on the package, included with the packing list, or otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the statement: "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN2910."

Contrary to the above, on (date), the licensee (transported/delivered to a carrier for transport) (amount) of (licensed material), as an excepted package-limited quantity of material, but the package was not prepared for shipment, as required, in accordance with 49 CFR 173.421. Specifically, [Identify the specific deficiencies which were noted].

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.424 excepts instruments and articles containing radioactive material and their packaging, from the specification packaging, shipping paper and certification, marking and labeling requirements, provided, among other things, that (Insert here the applicable item(s) from the below list).

- (1) each package meets the general design requirements in 49 CFR 173.410.
- (2) the activity of the instrument or article does not exceed the relevant limit listed in Table 7 of 49 CFR 173.425. 49 CFR 173.425 lists the activity limit for each instrument and article containing (Special form solid/ normal form solid/...) radioactive material as ($10^{-2} A_1 / 10^{-2} A_2 / \dots$).
- (3) the total activity per package does not exceed the relevant limit listed in Table 7 of 49 CFR 173.425. 49 CFR 173.425 lists the total activity limit per package for instrument and articles containing (Special form solid/ normal form solid/...) radioactive material as ($A_1 / A_2 / \dots$).
- (4) the radiation level at 10 centimeters (4 inches) from any point on the external surface of any unpackaged instrument or article does not exceed 0.1 millisievert per hour (10 millirem per hour).
- (5) the radiation level at any point on any external surface of the package does not exceed 0.005 millisievert per hour (0.5 millirem per hour), or for exclusive use domestic shipments, 0.02 millisievert per hour (2 millirem per hour).
- (6) the nonfixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a).
- (7) with exceptions not applicable here, the package does not contain more than 15 grams of uranium-235.
- (8) the package is otherwise prepared for shipment in accordance with 49 CFR 173.422. 49 CFR 173.422 requires, in part, that an excepted package of radioactive material, prepared for shipment in accordance with 49 CFR 173.424, must, be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the packing list, or otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the statement: "This package conforms to the conditions and limitations specified in 49 CFR 173.424 for radioactive material, excepted package-instruments or articles, UN2910."

Contrary to the above, on (date), the licensee (transported/delivered to a carrier for transport) (amount) of (licensed material), as an excepted package-instruments or articles, but the package was not prepared for shipment, as required, in accordance with 49 CFR 173.424. Specifically, [Identify the specific deficiencies which were noted].

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.475 requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror must insure by examination or appropriate tests, that the packaging is proper for the contents to be shipped, e.g., 49 CFR 173.427(a) requires that, unless excepted by §173.427(d), low specific activity (LSA) materials and surface contaminated objects (SCO), must be packaged in accordance with 49 CFR 173.427(b) or (c).

Contrary to the above, on (date), the licensee transported (LSA materials/SCO) in a package which was not authorized for that material pursuant to 49 CFR 173.427. Specifically, the materials were packaged in (describe the package and state why it did not meet the applicable condition(s) in §173.427, for example, why a strong-tight container did not: (1) meet the general design requirements of 49 CFR 173.410; (2) contained greater than an A₂ quantity,).

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.427(a)(6) requires, in part, that packages offered for domestic transportation containing low-specific activity (LSA) material or surface contaminated objects (SCO), which are required by 49 CFR 173.427 to be consigned as exclusive use, are excepted from marking and labeling requirements of 49 CFR Parts 171-177, provided that the exterior of each nonbulk package is stenciled or otherwise marked “Radioactive-LSA” or “Radioactive-SCO” as appropriate, and nonbulk packages that contain a hazardous substance are stenciled or otherwise marked “RQ” in association with the above description.

Contrary to the above, on (date), the licensee transported, in a domestic shipment, (LSA materials/SCO) in a nonbulk package required by 49 CFR 173.427 to be consigned exclusive use, and the exterior of the packages was not marked or stenciled (“Radioactive - LSA”/“Radioactive-SCO”).

This is a Severity Level _____ violation (Section 6.8).

or

Contrary to the above, on (date), the licensee transported, in a domestic shipment, (LSA materials/SCO) containing (specify) terabecquerels ((specify) curies) of (specify the nuclide(s)), which is a reportable quantity of a hazardous substance pursuant to 49 CFR 171.8 and Table 2 of Appendix A to 49 CFR 172.101, in a nonbulk package required by 49 CFR 173.427 to be consigned exclusive use, and the exterior of the packages was not stenciled or otherwise marked “RQ.”

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.475 requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror must insure by examination or appropriate tests, that the external radiation and contamination levels are within the allowable limits in 49 CFR Parts 171-178. 49 CFR 173.441(a) requires in part, with exceptions not applicable here, that each package of radioactive materials offered for transportation be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 millisievert per hour (200 millirem per hour) at any point on the external surface of the package.

Contrary to the above, on (date), the licensee (transported outside the site of usage, as specified on the NRC license, or on a public highway) / (delivered to a carrier for transport) (licensed material) in a package that arrived at its destination with a measured radiation level of approximately (specify) millisievert per hour (per hour).

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.475 requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror must insure by examination or appropriate tests, that the external radiation and contamination levels are within the allowable limits in 49 CFR Parts 171-178. 49 CFR 173.443(a) requires, in part, with exceptions not applicable here, that for beta and gamma emitting contaminants, the level of non- fixed (removable) radioactive contamination on the external surfaces of each package offered for transport, at the beginning of transport,, not exceed 0.4 Becquerel per square centimeter (22 disintegrations per minute per square centimeter) on any single wiping material, determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and averaging over the surface wiped. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the non-fixed contamination levels.

Contrary to the above, on (date), the licensee delivered to a carrier for transport a package which contained (licensed material), and the licensee did not determine the non-fixed contamination level prior to offering the package for transport.

This is a Severity Level _____ violation (Section 6.8).

Contrary to the above, on (date), the licensee delivered to a carrier for transport a package which was determined to have non-fixed contamination caused by (nuclide), a (beta/gamma) emitting radionuclide, of approximately (specify) disintegrations per minute per square centimeter averaged over the surface wiped.

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.448(a) requires that each shipment of radioactive materials be secured in order to prevent shifting during normal transportation conditions.

Contrary to the above, on (date) , the licensee (transported outside the site of usage, as specified on the NRC license, or on a public highway) / (delivered to a carrier for transport) a package containing (licensed material) which was not properly secured to prevent shifting during transport. Specifically, (state how/why the package was not properly secured, what happened, etc.) .

This is a Severity Level_____violation (Section 6.8).

49 CFR 173.466 requires, in part, that Type A PACKAGING designed for liquids shall be capable of withstanding the tests described in section 173.466(a)(1) and (2).

49 CFR 173.461 requires, in part, that compliance with the test requirements in section 173.466 shall be shown by any of the methods prescribed in section 173.461(a)(1)-(4), or by a combination of these methods appropriate for the particular feature being evaluated.

Contrary to the above, on (date) , the licensee (transported outside the site of usage, as specified on the NRC license, or on a public highway) / (delivered to a carrier for transport) (amount) of (licensed material) in liquid form, a quantity that requires Type A packaging, in a (specify the container, e.g., cardboard box) that had not been tested or evaluated for compliance with the test requirements in section 173.466.

This is a Severity Level_____violation (Section 6.8).

49 CFR 173.475 requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror must insure by examination or appropriate tests, that: (1) the packaging is proper for the contents to be shipped; (2) the packaging is in unimpaired physical condition, except for superficial marks; (3) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed. 49 CFR 173.415 lists the packages that are authorized for shipment to contain quantities of Class 7 (Radioactive) material not exceeding the A_1 or A_2 value, as appropriate.

Contrary to the above, on (date) , the licensee (transported outside the site of usage, as specified on the NRC license, or on a public highway) , (amount) of (licensed material) , a quantity not exceeding the (A_1 / A_2) value, in a packaging which was not authorized pursuant to 49 CFR 173.415. Specifically, (state how/why the package was not an authorized Type A package (e.g., a damaged/leaking drum was offered, a gauge device was shipped without retracting the source, etc...)) .

This is a Severity Level_____violation (Section 6.8).

49 CFR 173.475 requires, in part, that before each shipment of any radioactive materials package, the shipper ensure by examination or appropriate tests that each closure, valve,

or other opening of the containment system through which the radioactive content might escape is properly closed and sealed.

Contrary to the above, on (date), the licensee failed to examine or test the (specify valves, seals, etc.) of a package containing (licensed material) before delivering the package to a carrier for transport. [If appropriate, add a sentence to describe the result: "This resulted in (briefly describe what leaked, etc.)"]

This is a Severity Level _____ violation (Section 6.8).

49 CFR 173.476(a) requires, in part, that each shipper of special form radioactive materials maintain on file, for at least one year after the latest shipment, a complete safety analysis including documentation of any tests, demonstrating that the special form material meets the requirements of 49 CFR 173.469. 49 CFR 173.469(b) specifies the tests to be conducted for the safety analysis.

Contrary to the above, as of (date), the licensee shipped packages containing (licensed material) in special form, and did not maintain for a period of at least one year following each shipment documentation that the special form material meets the requirements of 49 CFR 173.469.

This is a Severity Level _____ violation (Section 6.8).

or

Contrary to the above, as of (date), the licensee shipped packages containing (licensed material) in special form, and the special form radioactive material had not undergone the required safety analysis to determine that it met the requirements of 49 CFR 173.469.

This is a Severity Level _____ violation (Section 6.8).

49 CFR PART 177 CARRIAGE BY PUBLIC HIGHWAY

49 CFR 177.817(e) requires, in part, that the driver of a motor vehicle containing hazardous material ensure that the shipping paper required by 49 CFR 177.817(a) is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, (i) when the driver is at the vehicle's controls, the shipping paper shall be: (a) within the driver's immediate reach while the driver is restrained by the lap belt; and (b) either readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle; (ii) when the driver is not at the vehicle's controls, the shipping paper shall be: (a) in a holder which is mounted to the side of the door on the driver's side of the vehicle; or (b) on the driver's seat in the vehicle. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

Contrary to the above, on (date), the licensee transported (licensed material) outside the site of usage, as specified on the NRC license, or on a public highway, and the driver of the vehicle did not ensure that the shipping paper was readily available in the driver's compartment, as required. Specifically, [State where the shipping paper was and why it was not accessible].

This is a Severity Level _____ violation (Section 6.8).

49 CFR 177.834(a) requires, in part, that packaging not permanently attached to the motor vehicle and containing radioactive material must be secured against movement within the vehicle on which it is being transported, under conditions normally incident to transportation.

Contrary to the above, on (date), the licensee transported (licensed material) outside the site of usage, as specified on the NRC license, or on a public highway, and the package was not secured against movement within the vehicle. Specifically, [State how/why the package was not considered to be secured].

This is a Severity Level _____ violation (Section 6.8).

49 CFR 177.842 requires, in part, that packages of radioactive materials be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on (date), the licensee transported a package containing (licensed material), outside the site of usage, as specified on the NRC license, or on a public highway, and the package was not blocked and braced such that it could not change position during conditions normally incident to transportation. Specifically, [State how/why the package was not sufficiently blocked and braced and what happened as a result].

This is a Severity Level _____ violation (Section 6.8).