

NRC INSPECTION MANUAL

ARCB

INSPECTION MANUAL CHAPTER 0308 ATTACHMENT 3 APPENDIX D

TECHNICAL BASIS FOR PUBLIC RADIATION SAFETY SIGNIFICANCE DETERMINATION PROCESS

Effective Date:

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ATTACHMENTS

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0308.03D-01 INTRODUCTION

The Public Radiation Safety cornerstone is made up of multiple program areas which have a potential to impact public health and safety: Radioactive Material Control, Radioactive Effluent Release, Radioactive Environmental Monitoring, Transportation, Land Disposal of Radioactive Waste and Physical Protection of Radioactive Material. The Public Radiation Safety SDP is used to assess the significance associated with findings in these areas. The findings are the result of NRC inspections—typically under inspection procedure 71124, “Radiation Safety, Public and Occupational”—self-revealed, or are identified by NRC licensees. The Public Radiation Safety SDP is designed to assess risk for routine plant operation or abnormal operational occurrences; it does not assess significance resulting from accident conditions. This SDP assesses the risk of licensee non-compliance with regulatory requirements and licensee programs and procedures established to ensure compliance with regulatory requirements. Regulatory requirements, values, and limits were used to inform risk thresholds (i.e., Green, White, Yellow, and Red) for this cornerstone.

As described in SECY-07-0112, when the Reactor Oversight Process (ROP) was first developed, it was recognized that probabilistic risk assessment techniques could not generally be applied to the ROP cornerstones of physical security, emergency preparedness, and radiation safety. Therefore, to establish the thresholds for categorizing the significance of findings, expert panels were formed during the ROP development to define those thresholds. In part, these panels were guided by what the expected agency response should be for various types of licensee performance deficiencies. The same philosophy is still used in the current formulation of the Public Radiation Safety SDP.

Additionally, when this SDP was first developed, “public confidence” was an NRC strategic plan goal. In order to align the SDP with that goal, a “public confidence factor” was used to determine the significance threshold of certain findings in the Public Radiation Safety cornerstone. In implementing this approach, the NRC and its external stakeholders recognized that a licensee’s control of its radioactive material is a significant issue for members of the public; even when very low levels of radioactive material are involved. Because of this, the

Public Radiation Safety SDP can impart a higher level of significance than would be warranted based solely on the risk from exposure to the radioactive material. The original thresholds of significance that were developed with public confidence in mind remain appropriate for the Public Radiation Safety cornerstone. However, as described in SRM-COMSECY-06-0023 (ADAMS Accession No. ML061380645), inspection findings should have a basis grounded in the SDP and their significance should not be based solely on the contribution related to public confidence.

In subsequent years, rather than focus inspection guidance on strategic goals, the staff has refocused these documents on the Principles of Good Regulation, of which Openness is one. The staff views public confidence as being bolstered by the Principle of Openness, in that a decision-making process that is open to the public and decisions that are founded on a risk-informed consideration of the circumstances involved with each case will foster the public's confidence in the outcomes. The NRC's process for significance determination encourages these behaviors. For example, in keeping with the principle of Openness, the NRC will communicate the basis for its significance determinations in inspection reports and provide opportunities for licensees to provide information for the NRC to consider during the Significance and Enforcement Review Panel (SERP) process. Lastly, these activities will continue to be conducted in a such a manner that they will be scrutable from an external stakeholder perspective.

0308.03D-02 GUIDANCE

02.01 Radioactive Effluent Release Program

This branch of the SDP focuses on the licensee's radioactive effluent release program. It evaluates the significance of findings related to the release of radioactive gaseous and liquid effluents and failures to implement the program.

The regulatory basis for requiring radiological effluent monitoring programs is provided in 10 CFR 20.1302, 10 CFR 50.36a and licensee-specific Technical Specifications (TS). 10 CFR 20.1302 requires that licensees take appropriate surveys of the unrestricted and controlled areas and effluents released into these areas to demonstrate compliance with the dose limits for individual members of the public. 10 CFR 50.36a requires licensees to establish Technical Specifications (TS) to keep releases of radioactive materials ALARA and to submit annual reports to the NRC describing the principle radionuclides in gaseous and liquid effluents. 50.36a provides numerical guidance via Appendix I to 10 CFR Part 50 for establishing limiting conditions for operation to ensure effluents from light-water cooled reactors are ALARA. Implementation of these requirements is described in plant-specific TS and, typically, further described in licensee-controlled Offsite Dose Calculation Manuals (ODCM). Although not specified by 10 CFR 50.36a, the NRC's Standard Technical Specifications (STS) and many operating reactor TS require that licensees include solid waste disposed as part of their Annual Radioactive Effluent Release Report. Additionally, licensees are required by 10 CFR 20.1301(e) to comply with the EPA's environmental radiation standards in 40 CFR Part 190. As discussed in the Federal Register (49 FR 2859), for licensees emitting direct radiation that is indistinguishable from background radiation levels, maintaining doses from effluents below the Appendix I design objectives demonstrates compliance with 40 CFR 190. Licensees who have radioactive sources that cause direct radiation levels that are above background must account for doses that result from direct radiation in addition to doses from effluents when demonstrating compliance with 10 CFR Part 20.1301(e).

To evaluate the significance of a finding in this portion of the SDP, the calculated dose from the effluent release must be known. Licensees typically describe how these calculations are performed in their ODCMs. As the dose to a member of the public from the radioactive effluent increases, so does the significance. However, when substantial failures to implement an effluent program occur, the NRC can issue a White finding regardless of the resultant dose to a member of the public.

A Green significance is given to findings involving an effluent release, where the licensee had an impaired ability to assess dose, which resulted in doses to members of the public that do not exceed the values in Appendix I to 10 CFR Part 50 and 10 CFR 20.1301(e) (or 40 CFR Part 190). The basis for the Green finding is that no ALARA objectives or regulatory limits were exceeded; however, the licensee's ability to assess dose was degraded.

A White significance is given to those findings that involve a substantial failure to implement the radiological effluent program. The basis for issuing a White finding in these cases can be found in SECY-07-0112 and stems from lessons learned following a significant uncontrolled liquid effluent release event at an NRC-licensed, pressurized water reactor. In this event, the NRC concluded that the radiological impact of the release was insignificant (i.e., less than 1 mrem). However, because the licensee failed to assess the potential impact to the public and did not adequately control the release of a significant amount of licensed material, the NRC determined that a supplemental inspection of the site was warranted. Such an outcome is commensurate with that which would result from the issuance of a White finding.

The criteria for a substantial failure to implement the effluent program is a loss of effluent controls to an extent such that: (1) a substantial potential existed for exceeding the public ALARA dose criteria, but fortuitous events prevented the dose from exceeding ALARA thresholds; or (2) the licensee did not identify or evaluate the event when a compliant implementation of their effluent program would have alerted the licensee to the release. The SDP makes use of terminology such as "significant" and "gross" to ensure that findings of very low radiological significance are not dispositioned as White. The staff's intent is to identify findings that indicate additional NRC inspection is needed and to disposition those findings as White.

A White significance is given to those findings involving effluent release in which the calculated dose to a member of the public is greater than the values in Appendix I to 10 CFR Part 50 and/or 10 CFR 20.1301(e) but does not exceed 0.1 rem. The basis for the White finding is that regulatory requirements related to maintaining radioactive effluents ALARA were exceeded, but the resultant dose is still below the annual public dose limit of 0.1 rem.

A Yellow significance is given to those findings which involved an effluent release in which the calculated dose to a member of the public is greater than 0.1 rem but does not exceed 0.5 rem. The basis for the Yellow finding is that the annual public dose limit of 0.1 rem was exceeded. This represents a violation of a regulatory standard.

A Red significance is given to those findings which involved an effluent release in which the calculated dose to a member of the public is greater than 0.5 rem. The basis for the Red finding is that the 10 CFR 20.1301 annual public dose limit of 0.1 rem is exceeded by a substantial margin. The value of 0.5 rem was chosen because it represents the upper limit that 10 CFR Part 20 would allow, based on specific authorization, for a limited time basis. However, without prior NRC authorization, the dose represents a violation of a regulatory standard.

02.02 Radiological Environmental Monitoring Program

This branch of the SDP focuses on the licensees radiological environmental monitoring program. It evaluates the significance of findings involving sampling and analysis of environmental media for the presence of licensed radioactive material released in gaseous and liquid effluents.

The regulatory basis for requiring radiological environmental monitoring programs is provided in 10 CFR 20.1302 and 10 CFR 50.36a. 10 CFR 20.1302 requires licensees take appropriate surveys of the unrestricted and controlled areas and effluents released into these areas to demonstrate compliance with the dose limits for individual members of the public. 10 CFR 50.36a requires licensees to establish Technical Specifications to keep releases of radioactive materials ALARA and provides numerical guidance via Appendix I to 10 CFR Part 50 for establishing limiting conditions for operation to ensure effluents from light water-cooled reactors are ALARA. 10 CFR 50 Appendix I directs licensees to establish surveillance and monitoring programs that provide data on measurable levels of radiation and radioactive material in the environment to evaluate the relationship between the quantities of radioactive materials released in effluents and resultant radiation doses to individuals from principal pathways of exposure. Licensees are to identify changes in the use of unrestricted areas (e.g., for agricultural purposes) to permit modifications in the monitoring program for evaluating doses to individuals from principal pathways of exposure. Implementation of these requirements is described in plant-specific Technical Specifications and, typically, further described in the licensee-controlled ODCM.

Radiological environmental monitoring is important for commercial reactor operations. During normal operations, including anticipated operational occurrences, environmental monitoring verifies the effectiveness of the plant systems used for controlling the release of radioactive effluents and direct radiation. It also is used to confirm that the levels of radioactive material in the environment and direct radiation exposures to members of the public do not exceed the projected values used to license the plant. Routine environmental monitoring stations may also be used during an accident to help estimate radiological releases to the environment; however, they are not required to be maintained for this purpose. Instead, licensees use mobile field teams capable of taking real-time measurements as the primary means to monitor site environs during an accident. Therefore, this branch of the SDP does not include accident assessment issues. For findings involving the use and maintenance of emergency field team capabilities the Emergency Preparedness SDP is to be used.

To evaluate the significance of a finding in this portion of the SDP, the licensee's performance in assessing the impact of its radioactive effluent releases on the environment surrounding the plant must be known. A Green significance is given to findings in environmental monitoring. The basis for the Green findings, as described in SECY-07-0112, is that the radioactive environmental monitoring program is a verification process, and findings that are greater than very low significance would be captured by the Radioactive Effluent Release Program branch. This distinction clarifies the entry criteria into the separate SDPs that cover effluents and the environmental monitoring. Therefore, when the environmental monitoring program identifies unexpected radiological conditions in the environment, the performance deficiencies should be assessed under the Radioactive Effluent Program branch.

02.03 Radioactive Material Control Program

This branch of the SDP focuses on the licensee's radioactive material control program. It assesses the significance of findings related to the licensee's failure to adequately control licensed material in accordance with the regulations and its program and procedures. This is the licensee's program which conducts radiation surveys of tools, equipment, and material (not personnel) that have the potential to have licensed material in or on it.

The regulatory basis for this program is contained in 10 CFR Part 20. 10 CFR Part 20, Subpart K - Waste Disposal, contains the acceptable ways to dispose of licensed radioactive material. Additionally, 10 CFR Part 20, Subpart F - Survey and Monitoring, contains the requirement that a radiation survey must be performed to assess the potential radiological hazard of licensed radioactive material. Also, 10 CFR 20, Subpart I - Storage and Control of Licensed Material, contains the requirements for the security and control of licensed material.

Any equipment, or material, that came into contact with licensed material or that had the potential to be contaminated with radioactive material of plant origin and is to be removed from the facility must be surveyed for the presence of licensed material. This is because NRC regulations, with one exception in 10 CFR 20.2005, provide no minimum level of licensed material that can be disposed of in a manner other than as radioactive waste or transferred to a licensed recipient; as described in 10 CFR 20.2001. In the absence of clearance limits in 10 CFR Part 20, licensees must perform a radiation survey of potentially contaminated items to ensure that no detectable licensed material is released from their control. Information and guidance on an acceptable radiation survey methodology to detect the presence of licensed radioactive material was issued by the NRC in Circular 81-07, Information Notice 85-92, and Information Notice 88-22.

To evaluate the significance of a finding in this portion of the SDP, the calculated dose to a member of the public from the licensed radioactive material must be known. As the dose to a member of the public from the radioactive material increases, so does the significance. Individuals who have not been classified by the licensee as occupational workers are sometimes permitted access to a licensee's restricted area for job related or public information purposes. Such individuals are either physically escorted or are granted limited unescorted access following the successful completion of appropriate orientation training and security screening. Exposures received by such individuals (i.e., workers who have not been classified as occupational workers) resulting in a radioactive material control finding will be evaluated using this SDP.

Discrete radioactive particles (also known as hot particles or fuel fleas) are handled differently because the dose from a discrete radioactive particle generally does not result in a total effective dose equivalent (TEDE) dose as defined in 10 CFR Part 20. Specifically, the dose from the particle is typically to a very small localized area of the skin and is not equivalent to the stochastic risk from a TEDE dose. However, if the discrete radioactive particle is of such a magnitude that a TEDE dose (e.g., ≥ 1 mrem) is received, then the finding should be assessed through the radioactive material control SDP. While the skin dose from a discrete radioactive particle is not assessed here, except as described above, isolated events can still result in a Green finding. For more significant performance issues that result in discrete radioactive particles (e.g., several people impacted), the staff should consider using the qualitative significance determination approach described in IMC 0609, Appendix M.

A Green significance is given to those situations where the calculated dose does not exceed 0.005 rem TEDE. The basis for the Green finding is that no regulatory limits were exceeded

and it is a dose value comparable to a Green finding in Radioactive Effluent Release Program SDP (i.e., it is comparable to the values in Appendix I to 10 CFR Part 50, which defines ALARA for radioactive effluents).

A White significance is given to those situations where the calculated dose to a member of the public from the licensed radioactive material is greater than 0.005 rem, but does not exceed 0.1 rem. The basis for the White finding is that regulatory requirements related to maintaining radioactive effluents ALARA were exceeded, but the resultant dose is still below the annual public dose limit of 0.1 rem.

A Yellow significance is given to those findings in which the calculated dose to a member of the public from the licensed radioactive material is greater than 0.1 rem but does not exceed 0.5 rem. The basis for the Yellow finding is that the annual public dose limit of 0.1 rem was exceeded. This represents a violation of a regulatory standard.

A Red significance is given to those findings in which the calculated dose to a member of the public from the licensed radioactive material is greater than 0.5 rem. The basis for the Red finding is that the annual public dose limit of 0.1 rem was exceeded by a substantial margin. The value of 0.5 rem was chosen because it represents the upper limit that 10 CFR Part 20 would allow, based on specific authorization, for a limited time basis. Without prior authorization, the dose represents a violation of a regulatory standard.

02.04 Transportation

This branch of the SDP focuses on the licensee's radioactive material transportation program. It assesses the significance of findings involving the licensee's failure to comply with requirements for the safe transport of radioactive materials on public roadways in accordance with NRC and Department of Transportation (DOT) regulations. This SDP is intended to be used for those radioactive material shipments classified as Schedule 5 (Low Specific Activity-1) through 11 (Fissile Material) in NUREG-1660, U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments. The regulatory basis for the transportation program is contained in 10 CFR Parts 20 and 71. Part 20 includes requirements to manifest transported material, to survey material and provide notifications when certain limits are exceeded. 10 CFR 71.5 requires, in part, that licensees engaged in transportation of licensed material comply with the applicable requirements of 49 CFR 107, 171-180, and 390-397 that are appropriate to the mode of transport.

The NRC and DOT regulations contain definitions and activity limits for Type A quantities of radioactive material. These activity limits were established using the International Atomic Energy Agency's (IAEA) Q-System as described in SSG-26, "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material." In general, for external exposure scenarios the Q-System assumes a dose of 5 rem at 1 meter from the package in a 30-minute period. The exposure period of 30 minutes at 1 meter is a cautious judgement of the incidental exposure of persons initially present at the scene of an accident; it is assumed that subsequent recovery operations take place under health physics supervision and control (e.g., HAZMAT specialists). The Q-value is an activity for each radionuclide that depends on the pathway being considered (i.e., external photon, external beta, skin, ingestion and submersion). For inhalation, ingestion and skin dose scenarios the Q-System makes further assumptions to reasonably approximate the radiological conditions that would result from an accident involving a radioactive material shipment. However, each of the scenarios uses 5 rem as the reference dose from which to calculate the corresponding activity. The activity that corresponds to the

most restrictive external dose (i.e., the photons and beta dose) is the A_1 (i.e., special form) value. Whereas, the A_2 (i.e., non-special form or dispersible) value is calculated from either the most restrictive of the internal and skin dose contributors or the A_1 value.

The background of the Q-System provides tools useful in explaining the thresholds for transportation findings. This is because the assumptions included in the system can serve as a basis from which to set the level of nominal risk that is associated with the transportation of radioactive material. For example, if a finding would introduce challenges to emergency response such that responders would be excessively delayed in their action, such a finding would be dispositioned applying the 30-minute exposure time period that is assumed in the system. Similarly, findings that impact external doses from packages would be dispositioned considering the external doses assumed in the Q-System.

Incorrect Packaging Used

When determining the significance of transportation findings, it is important to first determine if the correct packaging was used for the type of material being transported. 49 CFR 173.431 provides activity limits for Type A and Type B packages.

In addition to definitions, descriptions and limits provided in 49 CFR 173.403, LSA material and surface contaminated objects (SCO) are assigned specific conditions of transport in 49 CFR 173.427. For example, one of the conditions for transporting LSA and SCO is a limitation on the exposure level at a distance from the unshielded material of 1 rem/hr at 3 meters. This exposure scenario is similar in radiological significance to the level of exposure that serves as the basis for the Type A quantity limits in the Q-System. It is important to note that it is possible for an LSA or SCO shipment to contain activity that exceeds a Type A quantity. However, as long as the exposure level at 3 meters from the unshielded material does not exceed 1 rem/hr and other conditions on the transport of LSA and SCO are satisfied per 49 CFR 173.427 (e.g., conveyance-specific activity limits), the material can be offered for transport in accordance with provisions of 49 CFR 173.427 and does not have to be shipped in an NRC-approved Type B package.

With the exception of certain LSA material and SCOs described above, the Type A quantity represents the threshold above which the NRC and DOT have determined that radioactive material should be offered for transport in a packaging that is certified by the NRC (i.e. Type B package). Shipments containing radioactive material at or below the Type A quantities are conducted using packagings designed to withstand normal conditions of transport. However, because of the excessive exposures to first responders and members of the public that can result from releases of radioactive material in excess of Type A quantities, packages used to ship this type of material are designed to withstand hypothetical accident conditions. The NRC certification process provides reasonable assurance that packages used to ship radioactive material in excess of Type A quantities can adequately perform under accident conditions.

A Green significance is given if a licensee offers for transport radioactive material that is below a Type A quantity in an incorrect packaging. The basis for this is that this material requires transport in packagings that are designed to withstand normal conditions of transport. In general, the different types of packagings used to transport Type A quantities of material are designed to withstand the normal conditions of transport. Therefore, there would be very low risk to the public if Type A material is incorrectly packaged.

If a shipment should have been completed using a Type B package, either because the

radioactive material exceeded the Type A quantity or because the shipment contained LSA/SCO that exceeded the applicable conditions for transport, then at least a White significance is assigned because shipment of those types of material requires packages that are designed to withstand hypothetical accident conditions, not just conditions of normal transport. Shipping this type of material in a package that is not certified to withstand hypothetical accident conditions would represent an increase in risk above the nominal case of transporting radioactive material; therefore, the finding is of at least low (White) safety significance. As multiples of the Type A quantity are exceeded the Yellow and Red significance is assigned because of the increased risk associated with the shipment and to allow for the appropriate level of NRC supplemental inspection.

Radiation Limits Exceeded

This portion of the SDP evaluates findings related to the licensee's failure to correctly package and transport licensed material, on the public roads, which resulted in a situation where the external and/or surface contamination regulatory limits for the package were exceeded. The regulatory basis for this portion of the SDP is found in 10 CFR 71.47, 49 CFR 173.441, and 49 CFR 173.443.

The radiation limits of a package offered for transport include limits for external radiation; removable (non-fixed) surface contamination; and the activity that can be contained within a package. Since non-compliances with packagings are addressed elsewhere in this SDP, this section of the SDP assumes that the correct packaging is used and focuses on external radiation levels and removable (non-fixed) surface contamination levels.

The external radiation limits vary as a function of shipment type (i.e. non-exclusive and exclusive use). Specific limits also exist as a function of distance from the package, such as the transport index (TI), and for the area occupied by the driver. These external radiation limits are found in 49 CFR 173.441 and are duplicated in 10 CFR Part 71.47. The limits for removable (non-fixed) surface contamination on a package are found in 49 CFR 173.443 (Table 9). These limits vary as a function of shipment type (i.e. non-exclusive and exclusive use), the type and quantity of nuclide in the package and the emitted radiation (i.e. alpha, and beta/gamma emitters). The removable surface contamination limits were derived from a radiological model in the 1961 Edition of the IAEA Transportation Regulations. This model considered the radionuclides that were most hazardous and in common use and determined that the pathways of exposure of concern were irradiation of the skin and ingesting and inhalation of material that is removed from the surface. The derived limits correspond to values that were generally accepted for laboratory and industrial plant working areas and are conservative in terms of time of exposure to transportation workers when compared to laboratory or plant workers. Similarly, the various external radiation level limits were derived from a combination of considerations which included acceptable exposures to transportation workers—from being near packages as part of their normal work duties and from having to hand-carry packages—as well as limits to protect undeveloped photographic film from x-ray radiation-induced fogging.

To evaluate the significance of a finding in this portion of the SDP, the external dose rate and/or the removable surface contamination levels on the package being offered for transport must be known. As the radiation and/or activity levels increase, so does the significance.

A Green significance is given to those findings in which a radiation limit was exceeded within the following constraints: (1) For external radiation levels, the package—and thus the radiation—was not accessible by the public and the dose did not exceed twice the applicable

limit; or (2) For surface contamination levels, the contamination did not exceed five times the applicable removable surface contamination limits. The basis for the Green finding is that a regulatory limit was violated but the radiological risk significance to the public was very low.

A White significance is given to those findings in which a radiation limit was exceeded within the following constraints: (1) For external radiation levels, either the package—and thus the radiation—was accessible to the public, or the package was not accessible to the public and it exceeded twice the applicable limit, but did not exceed five times the limit; or (2) For surface contamination levels, the surface contamination limit was exceeded by five times but did not exceed 50 times the limit. The basis for the White finding is that a regulatory limit was exceeded and there is an increased radiation risk to members of the public.

A Yellow significance is given to those findings in which a radiation limit was exceeded within the following constraints: (1) For external radiation levels, the external dose rate was exceeded by five times but did not exceed ten times the limit; or (2) For surface contamination levels, the removable surface contamination limit was exceeded by 50 times but did not exceed 100 times the limit. The basis for the Yellow finding is that the regulatory limit was exceeded such that there is a substantial radiological risk to members of the public.

A Red significance is given to those findings in which the external dose rate limit was exceeded by 10 times the limit. For surface contamination levels, a Red significance is given when the removable surface contamination limit was exceeded by 100 times with radioactive contamination spread in an unrestricted area. The basis for the Red finding is that the regulatory limit was greatly exceeded such that there is a high radiological risk to members of the public.

An accessible area is defined in this SDP as an area that can reasonably be occupied by a major portion of an individual's whole body. The definition of whole body can be found in 10 CFR 20.1003. For example, consider a shipment that consists of a package loaded directly on a flatbed trailer that is secured in place. An example of an inaccessible surface is the underside of the package, which is sitting directly on the trailer. It is improbable that any member of the public would access that location, assuming normal conditions of transport. Examples of accessible areas include the topside, underside, and outside of the trailer, the unlocked cab, accessible surfaces of the package, and the surrounding area two meters from the loaded package. When determining accessibility, the likelihood that a member of the public would access the area in question may be considered when determining if the envisioned public exposure scenario is reasonable. Finally, accessibility is not a factor that is considered if the dose rate on the external surface of the package is greater than two times the regulatory limit.

In addition to accessibility, consideration may be given to risk-informing findings associated with situations where only a small area of a package exceeds the radiation limits. In its response to Petition for Rulemaking (PRM) 20-9 and 34-1 (ADAMS Accession No. ML11116A176), the NRC provided a position relevant to compliance with the surface survey requirements of 10 CFR 20.1906. This position is also summarized in Health Physics Position (HPPOS) 13. The NRC stated that averaging radiation levels over a cross-sectional area of a probe of reasonable size is acceptable for demonstrating compliance with the requirements specified in 10 CFR 20.1906(d)(2). "A probe of reasonable size" was defined as: (1) the sensitive volume of the probe being small compared to the volume of the package being measured, and (2) the largest linear dimension of the sensitive volume of the probe being no greater than the smallest dimension of the package. The NRC made this position regarding 10 CFR 20.1906; however, the practice of averaging radiation levels over a cross-sectional area of a probe of reasonable

size to demonstrate compliance with other regulations that require radiation measurements on package surfaces (e.g., 49 CFR 173.441(a)) is generally acceptable.

Breach of Package during Transit

This portion of the SDP evaluates the significance of findings which involve the licensee's failure to properly package and transport licensed radioactive material, on public roads that resulted in a breach of the package. For purposes of risk significance determinations, a package breach means a loss of containment for a package; whether the radiological contents of the package were released, or not. If the licensee failed to meet the package-related transportation requirements, and this failure contributed to the breach, then a breach finding is appropriate. However, not all package-related deficiencies should be dispositioned using the package breach SDP. For example, failure to properly torque closure lid bolts (35 ft-lbs versus required 45 ft-lbs) is not a breach, assuming the licensee analysis demonstrates that package integrity, and thus material containment, would have been maintained during the normal conditions of transport.

DOT and NRC transportation regulations regarding packaging requirements are diverse. Generally, these requirements become more stringent as a function of several factors. As the quantity, type, and form (i.e., readily dispersible) of radioactive material varies (becomes more radiologically significant), then the potential impact of a package breach on the public dose increases. Consequently, NRC and DOT requirements for packaging design and testing become more stringent as the contents increase in radiological significance.

For Type A packages normal conditions of transport are assumed; this includes rough handling tests as specified in the DOT regulations (i.e., free drop, water spray, penetration and stacking tests). Thus, during normal conditions of transport Type A packages are designed to prevent the loss or dispersal of radioactive material contents and maintain radiation levels below limits. If a package breach occurs during transit with equal to or less than the normal conditions of transport and the licensee failed to meet transportation requirements (resulting in the breach), then a breach finding is appropriate. However, if a breach occurs under conditions more adverse than the rough handling tests, then a breach finding would not be appropriate unless it can be shown that licensee performance contributed to the conditions that resulted in the loss of containment.

Under certain transportation scenarios, the DOT regulations allow the use of General Design Packages (or Type Industrial Packages [IP]-1). These types of packages are expected to contain radioactive material that is less hazardous than more robust packages (e.g., Type A package) and, thus, are not subjected to testing requirements. Therefore, breach scenarios (assuming no dose to the public or first responders) involving general design packages (or IP-1) are assigned a very low safety significance (GREEN).

In certain situations, Type B package manufacturers may provide instructions on how to use a Type B package in a Type A application. These instructions may involve reduced torque values for the lid bolts, modified or eliminated leak tests, coverage of Type B packaging markings etc. In these cases (i.e., when a Type B package is used in a Type A application in accordance with vendor instructions), the finding will be dispositioned as if the package was a Type A package. Finally, the DOT regulations allow the use of certain types of IP when shipping certain types of LSA or SCO; therefore, for the purposes of this the SDP diagram, Type IP-2 and Type IP-3 packages are treated in the same manner as Type A packages.

While power reactor shipping history has demonstrated that serious mishaps are highly unlikely,

if a transportation incident occurs with a package breach, then public dose consequences could result. To address this, the "Package Breach" branch has a section that focuses on public and occupational doses that occur as a result of the loss of control of package contents. These are actual doses to real individuals, and depending on the level, would lead to either White, Yellow or Red findings. Note that for a member of the public, the dose would in almost all cases be an estimate determined by the licensee. Designated on-scene trained responders (e.g., local county HAZMAT emergency team) would be subject to the occupational dose limits.

To evaluate the significance of a finding in this portion of the SDP, the status of radioactive material being released to the public, the type of package that was used during transportation and actual radiation dose to members of the public and responders must be known.

A Green significance is given to those findings in which there was no loss of contents from the package and the radioactive material was offered for transport in less than a Type B package. An example could be a solidified radwaste liner, inside a Type A package where the closure lid was not tightened down. In this case, given the form of the radioactive contents, loss of control of the material is very unlikely; therefore, the finding would be of very low safety significance. Additionally, a Green significance is given to those findings involving a loss of contents from a general design package (or IP-1), provided there was no actual dose to a member of the public or a responder. The basis for the Green finding is that the radiological significance is very low in these cases.

A White significance is given to those findings in which there was a loss of contents from the package and the radioactive material was offered for transport in less than a Type B package (not including a general design package or IP-1). Additionally a White significance is given to those findings in which there was a loss of contents from any package less than a Type B package where actual doses were given to the public or responders and the dose to a member of the public did not exceed 25 mrem and/or the dose to a radiation worker did not exceed 5 rem. The basis for the White finding is that individuals received doses that were within regulatory limits but in excess of doses that are considered ALARA.

A Yellow significance is given to those findings in which there was a loss of contents from the package and the radioactive material was offered for transport in less than a Type B package, where the dose to a member of the public exceeded 25 mrem, but did not exceed 100 mrem, and/or the dose to a radiation worker exceeded 5 rem, but did not exceed 25 rem. The basis for the Yellow finding is that individuals received doses that were in excess of applicable limits.

A Red significance is given to those findings in which there was a loss of contents from the package and the radioactive material was offered for transport in less than a Type B package, where the dose to a member of the public exceeded 100 mrem and/or the dose to a radiation worker exceeded 25 rem. The basis for the Red finding is that individuals received substantial doses. In the case of members of the public, the doses exceeded the public dose limit. In the case of occupational workers, the doses exceeded five times the dose limit.

Type B packages are designed to withstand normal conditions of transport as well as hypothetical accident conditions within leakage parameters (e.g., not leak in excess of an A quantity in less 1 week). These design considerations and criteria are contained in 10 CFR Part 71.73, and testing includes free drop, crush, puncture, fire, and water immersion. Given these rigorous design requirements, any breach of a Type B package in transit (in less than hypothetical accident conditions) is of a Yellow or Red significance, depending on whether the breach resulted in the release of package contents.

A Yellow significance is given to those findings in which there was no loss of contents from the package, but the radioactive material was offered for transport in a Type B package. The basis for the Yellow finding is the fact that Type B packages are certified to contain significant amounts of radioactive material (multiple thousand times the amount contained in a Type A package). These levels of radioactivity present substantial-to-high risks to members of the public and responders if the Type B package is not used in a manner consistent with the Certificate of Compliance such that a release of radioactive materials is possible. Since, in this case, the package contents were not released the significance is limited to substantial as indicated by a Yellow finding. An example of a Yellow finding is where a receiving facility finds the incoming package's drain valve open—presenting a direct pathway to environment—but, assuming normal conditions of transport, no potential for loss of control of materials occurred because of the type of material being offered for transport (e.g., dry irradiated components).

A Red significance is given to those findings in which there was a loss of contents from a Type B package in less than hypothetical accident conditions. The basis for the Red finding is the fact that Type B packages are certified to contain significant amounts of radioactive material (multiple thousand times the amount contained in a Type A package). These levels of radioactivity present substantial-to-high risks to members of the public and responders if the Type B package is not used in a manner consistent with the Certificate of Compliance such that a release of radioactive materials occurred. Since, in this case, the package contents were released the significance is high as indicated by a Red finding. An example of a Red finding is if, using the same “open valve” scenario for a Yellow finding above, the package contents were spent fuel because fission product gases could feasibly have been released continuously to the environs during the shipment.

The significance resulting from an accident that exceeds hypothetical accident conditions is beyond the scope of this SDP and should be determined using the qualitative significance determination approach described in IMC 0609, Appendix M.

Failure to Make Notifications or Provide Emergency Information

This portion of the SDP has four components which evaluate findings related to notification and emergency response information requirements for radioactive material being transported on public roadways. The regulatory basis for this portion of the SDP is found in 10 CFR Part 71, 49 CFR Part 172, and 10 CFR Part 20. The requirements in 49 CFR Part 172, Subpart G, Section 172.600 apply to any shipment which is required to have shipping papers. Shipments of excepted radioactive material packages (e.g., limited quantities without hazardous substances, radioactive instruments and articles, manufactured articles of uranium, or empty packages) can be exempt from the emergency response information requirements. NRC regulations (10 CFR 71.97) require advance notification to state governors and officials from participating Tribes for shipments of irradiated reactor fuel and nuclear waste under certain conditions. These notifications include quantity and form, and type of shipping container required. Notifications must be made in a timely manner to all the states or reservations of participating Tribes hosting the radioactive material shipment. Other NRC regulations (10 CFR 20.1906) require receivers of certain packages of radioactive materials to perform timely external and surface contamination radiation monitoring upon receipt of the packages. If applicable radiation limits are exceeded, the receiving licensee must then report the event to the final shipment carrier and the appropriate NRC Regional Office.

A White significance is given when the licensee did not adequately inform the state governor, the governor's designee, or the official from the participating Tribe prior to conducting a radioactive material shipment that met the criteria for notification in 10 CFR 71.97. The basis for the White finding is that the state or Tribe's public radiation safety measures could have been adversely impacted by the non-compliance such that they would not be able to meet their own requirements that are applicable to radioactive material in transit. If the licensee fails to meet a timeliness of notification requirement (i.e., notification not postmarked at least 7 days before the 7-day shipment period), then the finding is Green. Through the normal SERP process, the NRC can consider information provided by the licensee that would assist in dispositioning the significance of the finding as Green (e.g., letter from state or Tribal agency characterizing the impact of the non-compliance). Otherwise, the SDP assumes such non-compliances have a low to moderate safety significance.

A White significance is given when the licensee failed to provide emergency response information required by 49 CFR 172.602 such that the impact of the error or omission in the emergency response information would seriously hamper emergency response efforts in the event of an accident. The basis for the White finding is that the errors or omissions could result in responders encountering unknown hazards or delay responder actions such that exposure period assumptions of the Q-System are not reasonably applicable to the scenario being considered. Examples of violations that would seriously hamper emergency response efforts include, substantial errors or omissions (e.g., missing pages or uncommunicated hazards) in communicating the immediate hazards to health; risks of fire or explosion; and immediate precautions—or, if the aforementioned information is in an unusable/unreadable format. Additionally, discrepancies between the basic description information (e.g., proper shipping name and United Nations identification number) and the package markings could significantly hamper emergency response actions because responders could be confused as to which information applied resulting in delays to response actions. Licensees oftentimes use emergency information documents that are based on the DOT, Pipeline and Hazardous Material Safety Administration (PHMSA) Emergency Response Guidebook (ERG) to satisfy the requirements of 49 CFR 172.602. Staff can use the PHMSA ERGs as general guidelines for the scope and depth of information that is expected by radioactive material shippers and emergency responders; however, the NRC has not endorsed this guidance. Significance determinations should consider whether the information the licensee provided the carrier reasonably satisfies the information requirements of 49 CFR 172.602 and not if the information provided by the licensee exactly matches that which is included in a particular ERG.

A White significance is given if, during an actual emergency, the licensee does not respond in a timely manner, or had not provided the emergency response telephone number as required in 49 CFR 172.604 such that responders were not able to reach the person who is knowledgeable of the hazardous material being offered for transport in a timely manner. The basis for the White finding is that the non-compliance could delay responder actions such that exposure period assumptions of the Q-System are not reasonably applicable to the scenario being considered. "Timely," as used in this section of the SDP is in terms of the amount of time needed to support actual response efforts while in progress. The Q-System assumes that it is not likely for an individual to remain within 1 meter of a package for more than 30 minutes during an accident. Therefore, "timely" would normally be measured in terms of minutes from when responders make a call. In cases where no accident occurred, the significance of these findings would be Green.

A White significance is given if the licensee's receipt surveys show 1) the package's external radiation levels in excess of five times the Part 71.47 limits, or 2) the removable (non-fixed) surface radioactive contamination level in excess of five times the 49 CFR 173.443 limits, and

the licensee fails to make notifications to the final delivery carrier. NRC regulations at 20.1906 require licensees to notify the final carrier when the removable (non-fixed) contamination exceeds the limits in 10 CFR 71.47 and 10 CFR 71.87(i). The basis for the White finding is that a regulatory limit was exceeded by an excessive amount. If the surface contamination is the result of a leaking package, then assess the finding through the package breach SDP, as well.

Certificates of Compliance

This portion of the SDP evaluates findings related to the licensee's failure to properly package and transport in accordance with the requirements of its general or specific license. Physical damage or structural failure of a transport package is processed through the package breach flow chart.

Pursuant to 10 CFR 71.3, a licensee may not deliver or transport licensed material without a general or specific license. The general license for the use of an NRC-approved package is discussed in 10 CFR 71.17. Section 71.17 grants a general license to a licensee to transport or deliver to a carrier for transport licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC. Additionally, Section 71.5 requires the licensee to comply with the applicable DOT regulations in 49 CFR.

Usually, the form of approval issued by the NRC is a CoC. For purposes of readability, consider the CoC as discussed here to mean any NRC issued approval for a package. The CoC approves a specific package design, including a detailed description of allowable contents consistent with the use of the general license of Section 71.12. The CoC also lists the requirements or conditions for the use and maintenance of the package in block 4 of the CoC. Frequently, these conditions include references to the package's Safety Analysis Report (SAR) or procedures supplied by the CoC holder to the package owner or user. The user of the package must comply with the requirements of 10 CFR Part 71, the applicable regulations of 49 CFR, the CoC and their own transportation program instructions, including quality assurance requirements, to ship material.

This portion of the SDP has four components which evaluate findings related to the following: Design Documentation Deficiency, Maintenance/Use Performance Deficiency, Minor Contents Deficiency, and >1 Major Contents Deficiency.

A Green significance is given for the Design Documentation Deficiency component. These are findings in which there is a design documentation deficiency related to the maintenance or use of an NRC approved package. The deficiencies covered here are expected to be documentation non-compliances, not the failure to perform a required action. There are no findings of higher significance for this area. The basis for the Green is that these non-compliances would not be considered safety significant because the required action was performed and, often, the required documentation can be re-created with appropriate measures to show its creation after the actual performance of the activity.

A Green significance is given for the Maintenance/Use Performance Deficiency component. These are findings in which the licensee has failed to perform, or improperly performed, required actions related to the physical condition of the package. It does not include the physical failure of a package or the results from a physical failure, such as excessive exposures, personnel injury or property damage which are covered elsewhere in the SDP. There are no findings of higher significance for this area. The basis for the Green is that these non-compliances would not be considered safety significant because a single occurrence of failing to perform one of these individual actions will not usually result in a significant event.

A Green significance is given for the Minor Contents Deficiency component. These are findings where a specification regarding cask contents with very low safety significance required by the CoC was not met (e.g., the issue was not a temperature, pressure, geometry, weight, burnup, enrichment, or moderator specification nonconformance). There are no findings of higher significance for this area. The basis for the Green is that this type of deficiency would have very low risk significance relative to causing a radioactive release to the public or causing public or occupational exposure. If a radiation limit was exceeded or an overexposure resulted due to this deficiency, that finding would be handled through a different SDP branch.

For the >1 Major Contents Deficiency component, the significance is determined for a finding in which the package contained radioactive material where a critical parameter was outside the limits of the CoC, or that the closure/containment system was deficient. The critical parameters that are considered for this component of the SDP are as follows: a breach of the package, a radioactive material release, a failure to exercise adequate controls, or a dose exceeding a public or occupational dose limit. A White significance is given when only one critical deficiency was identified. A Yellow significance is given when more than one critical deficiency was identified. The basis for these significance levels is that as a given package contains more deficiencies, it is more likely to result in a public radiation exposure event. Furthermore, deficiencies such as these are risk significant in that they are more likely to lead to a criticality event, a breach of package, a radioactive release, the failure to exercise adequate controls, or a public or occupational dose exceeding NRC limits.

02.05 Licensing requirements for Land Disposal of Radioactive Waste

Low Level Burial Ground (LLBG) Nonconformance

The regulatory basis for this portion of the SDP is found in 10 CFR Part 61. 10 CFR 61.55 and 61.56 provide requirements for the classification and characterization of radioactive waste destined for disposal at a licensed land disposal facility. Determination of the acceptability of the waste for disposal is made by the applicable regulatory agency for the waste disposal facility; either NRC or the Agreement State. Agreement States have the authority under the Atomic Energy Act to promulgate regulations that are compatible with NRC's disposal regulations in 10 CFR Part 61. They also have the authority and responsibility to issue disposal facility licenses under their Part 61 compatible regulations, and to disposition a non-compliance by a licensee.

To evaluate the significance of a finding in this portion of the SDP, the quantity, Class, and form (i.e., readily dispersible) of radioactive material must be known. As the quantity, type, and form of radioactive material varies (increases), then the potential impact to members of the public, radiation workers, and the environment (licensed facility receiving the material) increases.

A Green significance is given to those findings in which the radioactive material was under-classified (e.g., the waste was classified as Class A, when it should have been Class B) and the under-classification did not result in improper disposal of the waste. Additionally, a Green significance is given to those findings involving violations of 10 CFR 61.55 that do not involve under-classification. The basis for the Green finding is that there is little to no risk to members of the public, radiation workers, and the environment.

A White significance is given to those findings in which the radioactive material was under-classified Class C waste (i.e., the waste was classified as Class A or B, when it should have been Class C). A White significance will also be given to those findings in which the radioactive

material was under-classified and the under-classification resulted in improper disposal of the waste with regard to 10 CFR 61.56. The basis for the White finding is that a regulatory limit was exceeded and there is an increased radiation risk to members of the public and radiation workers, and the environment.

There are no findings of significance greater than White in this portion of the SDP.

02.06 Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material (10 CFR Part 37)

This branch of the SDP provides a methodology for determining the significance of findings involving the physical protection of category 1 and category 2 quantities of radioactive material as required by 10 CFR Part 37. The purpose of 10 CFR Part 37 is to provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. In general, the SDP seeks to remain consistent with NRC Enforcement Policy outcomes of violations of material security requirements at non-power reactor facilities. However, consistent with the risk-informed approach to significance determination, this SDP allows the consideration of mitigating factors such as the defense-in-depth and relevant physical features of the material and the reactor facility—which may mitigate the likelihood of theft and diversion—to arrive at a conclusion that appropriately communicates the significance to the public, and the licensee, and that guides the application of the NRC’s inspection resources.

Findings that are not causal factors in the actual loss of radioactive material should not be dispositioned at greater than White significance per this SDP. If a finding results in the exposure of a member of the public, then the radioactive material control SDP should be consulted, as well. Additionally, this SDP results in White significance outcomes in the situations described below and pictured in the relevant figures of IMC 0609, App D. If a finding does not “trip” one of the criteria in the figure that applies to the violation being assessed, then the finding is Green. Findings that are causal factors in actual theft and diversion, or that meet other criteria for Traditional Enforcement as described in the NRC Enforcement Policy (e.g., impeding the regulatory process by failing to notify the NRC when required), would be dispositioned using the Traditional Enforcement, to determine the severity level of the associated violation, and this SDP, to determine the significance of the finding for assessment purposes.

Oftentimes, Part 37 violations result from errors in licensees identifying that radioactive material exceeds the category 2 threshold. In these instances, several Part 37 findings will be identified, and it may become necessary to evaluate the significance of the combined impact of multiple findings, as described in IMC 0612, App B regarding the documenting of related violations at the problem level. This approach is acceptable because the combination of multiple Part 37 violations may challenge the licensee’s ability to meet the General Performance Objectives as stated in 10 CFR 37.21(b) and 10 CFR 37.41(b). In these, cases the problem statement in the inspection report should include the General Performance Objective that was not met along with the individual violations that contributed to the failure to meet the objective.

The applicability of this SDP depends on where the radioactive material is located and what protective measures the licensee has put into place to protect the material. First, for radioactive material that is located within a protected area (PA), as defined by 10 CFR Part 73 and the licensee’s security plan, the physical protection measures required by 10 CFR Part 73 are expected to provide a level of protection equivalent to those required by 10 CFR Part 37; as

described in RIS 2015-15. The provisions of 10 CFR 37.11(b) allow a licensee with an NRC-approved 10 CFR Part 73 security plan to rely on the physical protection measures described in that plan to meet the physical protection requirements of 10 CFR Part 37, Subparts B and C to the extent that the 10 CFR Part 73 security program provides the equivalent level of protection for category 1 and category 2 quantities of radioactive material. Licensees should demonstrate how the radioactive material is protected (i.e., at a level that is equivalent with the requirements of 10 CFR Part 37, subparts B and C) within the PA in a security plan. Second, in cases, where radioactive material exceeding the category 2 limit is located within the PA and these activities are included in a security plan, as described in RIS 2015-15 (i.e., physical protection measures, material accountability and training), the licensee is exempt from Subpart B and C of Part 37, per 10 CFR 37.11(b). Therefore, the portions of this SDP that address non-compliances with 10 CFR Part 37, subparts B and C do not apply. If the radioactive material is located within the PA but is not adequately included in a security plan, then the finding should be dispositioned using this SDP with consideration given to the increased security that is provided through the Part 73 plan, as applicable. In these cases, although the material is not adequately included in a security plan, the NRC can verify whether the criteria of RIS 2015-15 were in fact met for the material. The basis for this approach is that the purpose of the PA is to protect material and equipment as described in 10 CFR Part 73 and, more specifically, the licensee's Part 73 security plan. Absent the licensee establishing protective measures for category 1 and category 2 radioactive material, as described in RIS 2015-15, the level of protection required by Part 37 may not be satisfied within the PA. Lastly, in cases where the radioactive material exceeding the category 2 limit is not located within the PA and a finding is identified, then the finding should be dispositioned using this SDP.

Failures to respond, investigate, or report per 10 CFR 37.49(d), 10 CFR 37.79(e) or 10 CFR 37.81, respectively, shall be dispositioned using Traditional Enforcement as violations that may impact the ability of the NRC to perform its regulatory oversight function to determine the severity level of the associated violation and this SDP, to determine the significance of the finding for assessment purposes.

Actual Loss of Material (Subpart A, B or C Finding and Subpart D Finding)

For the purposes of this SDP "loss of material" describes a situation where the location of material exceeding the category 2 limit is unknown by the licensee. To ensure that the staff's inspection efforts do not impede or otherwise affect any investigations, NRC staff should contact NRC's Office of Investigations to determine the appropriate course of action in those cases. Additionally, findings that are causal factors in actual theft and diversion would be dispositioned using Traditional Enforcement as violations that resulted in actual safety or security consequences to determine the severity level of the associated violation, and this SDP, to determine the significance of the finding for assessment purposes.

In 78 FR 16926, the NRC cited the Radiation Source Protection and Security Task Force conclusion that the International Atomic Energy Agency (IAEA) Code of Conduct serves as an appropriate framework for considering which radioactive material sources warrant protection under 10 CFR Part 37. In its 2010 report to Congress and the President, the Task Force found that category 1 and category 2 quantities of radioactive material are "levels of radionuclides that could result in a significant radiological exposure device (RED) or radiological dispersal device (RDD) event and therefore warrant enhanced security and protection." Thus, the loss of radioactive material in quantities exceeding the category 2 limit can significantly impact the public health and safety and common defense and security. This SDP uses the definitions of category 1 and 2 material found in the IAEA Code of Conduct.

A Red significance is given to those findings, whether at the licensee facility or in transport, that the NRC or licensee concludes is a causal factor in the loss of radioactive material exceeding the category 1 limit. The basis for the Red finding is that the loss of a category 1 quantity of radioactive material can result in an event of high radiological significance for the public because category 1 sources, can cause permanent injury to a person who handled them, or were otherwise in contact with them, for more than a few minutes.

A Yellow significance is given to those findings, whether at the licensee facility or in transport, that the NRC or licensee concludes is a causal factor in the loss of radioactive material exceeding the category 2 limit. The basis for the yellow finding is that the loss of a category 2 quantity of radioactive material can result in an event of substantial radiological significance for the public because category 2 sources, can possibly cause permanent or severe injury to a person who handled them, or were otherwise in contact with them, for a short time period (i.e., on the order of minutes to hours).

Subpart A, B or C Finding – Access by Individual who is not Trustworthy and Reliable

Trustworthiness and reliability are characteristics of an individual who is considered dependable in judgement, character and performance as determined based on the results of a background investigation. The requirements to ensure the trustworthiness and reliability of reviewing officials and personnel who have unescorted access to category 1 and category 2 quantities of radioactive material (or any device containing the material) are contained in Subpart B to 10 CFR Part 37. The objective of an access authorization program, as stated in 78 FR 16928, is to ensure that individuals who have unescorted access to radioactive material of category 2 quantity or greater are trustworthy and reliable and do not constitute an unreasonable risk to the public health and safety or common defense and security. This is primarily accomplished through a background investigation. Findings involving an individual who has not been adequately determined to be trustworthy and reliable and yet was granted unescorted access to radioactive material exceeding the category 2 limit will be dispositioned using this branch of the SDP; unless it is more appropriate to disposition them under the Physical Security Cornerstone.

As described in NUREG-2155, power reactor licensees may satisfy the requirements of Subpart B to 10 CFR 37 through programs established to meet personnel access authorization requirements for nuclear power plants in accordance with 10 CFR 73.56. In these cases, NRC security inspection personnel should be consulted to determine if the finding being dispositioned should be reviewed using an SDP in the Physical Security Cornerstone. Because access to PAs is controlled by Part 73.56 programs, this SDP should only be used to evaluate findings involving access authorization to radioactive material that is stored outside of the PA.

When dispositioning findings using this SDP, staff should consider if the violation would have impacted the licensee's final determination of trustworthiness or reliability. For example, either the background investigation is missing altogether, or the investigation is missing information that would normally be considered by the licensee in their determination of trustworthiness or reliability. In these cases, the finding would be White. The basis for the white finding is, as described in 78 FR 16928, individuals who have unescorted access to radioactive material that exceeds the category 2 limit could pose a risk to public health and safety and common defense and security because they could divert or steal, or aid in the diverting or stealing, of risk-significant radioactive material. Therefore, if a licensee allows unescorted access to radioactive material exceeding the category 2 limit to an individual who is not trustworthy and reliable, then this would represent an increase in baseline risk that is above the nominal level that is best

represented by a finding of White significance.

In situations where the licensee completes a timely and adequate background investigation, or supplements the existing background investigation to address the underlying performance deficiency, to obtain information which the licensee can use to conclude that the individual was in fact trustworthy and reliable at the time unescorted access was granted, then the finding would be Green—even if such actions are taken after the non-compliance is identified. The basis for the Green finding is that, although deficiencies existed in the process, the individual who was granted access to the material was in fact trustworthy and reliable at the time access was granted.

Subpart A, B or C Finding – Ineffective Security Zone or Deficient Security Zone and Deficient Detection Method

Subpart C of 10 CFR Part 37 provides the physical protection requirements that apply to radioactive material exceeding the category 2 limit. The combination of the requirements provides for defense-in-depth in the protection of the material through redundancy and diversity of equipment and methods of protection, as applicable. For example, as it relates to the protection of category 1 material, the licensee is required to 1) establish a security zone around the material which would limit access to the material; 2) establish the capability to monitor and detect all unauthorized entries into the security zone; and 3) have a means to immediately detect unauthorized removal of the radioactive material from the security zone. The physical protection of category 2 material is similar except that instead of the immediate detection of unauthorized removal of radioactive material, as provided by 37.49(a)(3)(i), the licensee is required to conduct a weekly verification that the material is present, per 37.49(a)(3)(ii). The collection of these requirements provides defense-in-depth that ensures that radioactive material that exceeds the category 2 limits is adequately protected against theft and diversion even when one, or more, non-compliances occur.

This SDP divides the physical protection provided by Part 37 into two layers. The first layer is provided by the security zone. The security zone includes (1) direct observation or physical barriers, and the equipment or methods to control access to the security zone; and (2) the equipment or methods to monitor and detect unauthorized access to the security zone. The second layer is provided by the material detection capability which includes, for category 1 material, the means of immediate detection of any attempted removal of the material from the security zone; and, for category 2 material, the means of weekly verification of the presence of the material.

An ineffective security zone is one where the licensee has failed to meet requirements in establishing a security zone such that a reasonable analysis would indicate the radioactive material is not protected from unauthorized access in a manner intended by 10 CFR Part 37. These findings would result from concurrent failures of the licensee's capability to control access to (10 CFR 37.47) and monitor and detect unauthorized access to the security zone without delay (10 CFR 37.49(a)(1) – (a)(2)). In general, these findings result from a failure of the licensee to establish a security zone (e.g., failure to identify that material was within the scope of Part 37), or a gross failure to maintain the effectiveness of a security zone (e.g., failure to control keys, combinations and failures to set alarms or detection systems). Deficiencies that do not render a security zone ineffective should be dispositioned using the deficient security zone process. A White significance is given to findings that result in ineffective security zones because they result in an excessive reduction in the protection of radioactive material exceeding the category 2 limit.

It is not likely that a PA would ever meet the criteria to be declared an ineffective security zone from a Part 37 perspective, although one example could be an unattended opening that allowed unauthorized access to the PA. When evaluating Part 37 findings that occur in the PA, it is appropriate to consider mitigating factors in the significance determination because of the very low likelihood that an unauthorized individual could successfully remove radioactive material from the PA without alerting the licensee to the nefarious activity. Other considerations that mitigate the significance of these types of events include the expected response of the licensee's guard force to attempted theft or diversion of category 1 or category 2 radioactive material from the PA; the physical form of the radioactive material (e.g., physical weight or size). The basis for this approach is that while Part 73 and Part 37 security plans have different purposes, scopes and threats bases, the overall level of security provided by Part 73 requirements provides reasonable assurance that theft and diversion of radioactive material from PAs is of a very low likelihood.

A deficient security zone is one in which there are one, or more, physical protection-related findings (10 CFR 37.47 and 37.49(a)(1) – (a)(2)); however, the non-conforming conditions underlying the finding(s) do not result in an ineffective security zone. In these cases, the security zone is considered able to serve its, but at a decreased level of effectiveness.

A deficient material detection capability is one which there are findings that impact the means to detect unauthorized removal of radioactive material from the security zone (10 CFR 37.49(a)(3)(i) or (ii)), as applicable with regard to the category of material.

If the findings being considered through this SDP result in a concurrent deficient security zone and a deficient material detection capability, then the significance of the finding(s) is White. The basis for the White significance is that the finding(s) result in an excessive reduction in the protection of radioactive material exceeding the category 2 limit.

If the findings being considered through this SDP do not result in a concurrent deficient security zone and deficient material detection capability, then the significance of the finding(s) is Green. The basis for the Green significance is that, even with the deficiencies, there exists sufficient defense-in-depth to provide reasonable assurance of the security of radioactive material that exceeds the category 2 limit such that there is a very low risk of theft or diversion of the material.

When evaluating lapses in coverage (e.g., failures of video surveillance or direct observation), the licensee is afforded an opportunity to provide their own estimate. However, if they choose to not provide an estimate then the NRC can use reasonable judgement. This judgement does not have to be scientific in nature, it can be based on knowledge of the site and conservative estimates on the amount of time it would take a person to perform the act being considered. NRC Health Physics inspection staff should coordinate with Physical Security inspection staff to develop time estimates.

Subpart D Finding – License Verification Issue

Part 37 requires licensees who are shipping radioactive materials that exceed the category 2 limit to verify, via methods described in 37.71, that the recipient is licensed to receive the type, form, and quantity of radioactive material (and for category 1 material, the at location where the material will be delivered). This verification ensures continuity of the physical protection of category 1 and category 2 material when it is transferred from one licensee to another. The

significance of failing to complete a license verification is realized when custody of the material is transferred to a recipient who is not licensed.

If a license verification issue results in transferring material exceeding the category 2 limit to an entity or location that is not licensed for the material and the licensee is unable to regain custody of the material, then the finding is Yellow if the material is category 2 and Red if the material is category 1. The basis for these significance outcomes is that permanently transferring radioactive material to an unlicensed entity is equivalent to a loss of material; therefore, the outcome is consistent with that case.

If the licensee delivers material to an entity or location not licensed for the material but regains custody of the material, then the finding is White. The basis for this significance is that it is assumed that the entity would not be capable of providing adequate protection of radioactive material exceeding the category 2 limit; therefore, the significance is equivalent to that presented by material that is in an ineffective security zone.

If a finding occurs in license verification and before the material is delivered to the recipient the licensee can either (1) recall/redirect the shipment, or (2) complete the verification, then the finding is Green. Additionally, if the licensee determines that the recipient was licensed to receive the material (even if the verification occurred after the material was delivered to the recipient), then the finding is Green. The basis for the Green significance is that the radioactive material was adequately protected because the material had not yet reached the point of transfer to the potentially unlicensed entity, or the recipient was in fact licensed.

Subpart D Finding – Preplanning and Coordination Issue

Licensees must complete certain requirements prior to shipping radioactive material that exceeds a category 2 quantity. These preplanning and coordination activities allow for recipients, and states, to establish the necessary conditions to adequately protect the material upon receipt and during transit. Some states will conduct vehicle inspections while certain types of radioactive material are in transit across their territory and they may wish to escort the transporting vehicle with law enforcement, as well.

The advance notification requirements in Part 37.75 that apply to the transport of category 1 quantities of radioactive material provide adequate notification times for the state officials to take actions they deem necessary. Findings involving advanced notification of a state are significant when the state's actions are adversely impacted (e.g., they are not able to establish a rendezvous for a vehicle inspection); this is consistent with the SDP outcomes for transportation findings involving violations of 10 CFR 71.97 notification requirements. Findings involving failures to coordinate no-later-than (NLT) arrival times and the expected shipment arrival times of category 2 material become significant when the receiving licensee is not able to provide adequate security of the material because the coordination failure. Additionally, if notifications of failure to arrive are delayed, this may delay response actions.

This SDP assumes that failures associated with preplanning and coordination adversely impact material security unless the licensee can provide information to the contrary. For example, if the licensee fails to provide advanced notification of a category 1 shipment to a state as required, the NRC will assume the state's functions will be impacted such that material security will be adversely affected, resulting in a White Finding. This outcome is consistent with findings involving failures to notify states under 71.97 as described in section 02.04 above. Similarly, if the licensee fails to coordinate the delivery (e.g., expected arrival time or NLT arrival time) of a

category 2 shipment with the recipient, or fails to follow-up if the shipment is not confirmed by the recipient by the NLT arrival time, then the NRC will assume the recipient is unaware of the delivery and is thus not capable of adequately protecting the material upon receipt or the licensee is not able to initiate a response upon failure of the material to arrive, resulting in a White Finding. However, if a recipient fails to confirm with the originator receipt of category 2 quantity of material, then the finding is Green. The basis for the Green is that the primary burden is placed on the originator until the shipment is confirmed received by the recipient.

The assigned significance of these types of findings can be lessened if the licensee can demonstrate a minimal adverse impact on material security resulted from the finding. For example, if the state was still able to meet its functions then the significance of the finding can be reasonably reduced, or if a licensee procedurally verifies the arrival of all radioactive material shipments at the receiving facility at the expected shipment arrival time, then this would mitigate the failure to establish a NLT arrival time. Or, if, for category 2 shipments, the carrier applies a tracking system that provides continuous active monitoring, which is in excess of the tracking required for a category 2 shipment. The basis for this is that a minimal impact on material security would not require a White finding.

Subpart D Finding – Physical Protection in Transit

Part 37 provides requirements for the physical protection of radioactive material while being transported from licensee to licensee. For category 1 material, these protections include redundant communications with continuously staffed movement control centers (MCC); continuous, active location tracking systems that provide positive confirmation of the location, status and control of the shipment; normal and contingency procedures; and drivers qualified to transport highway route-controlled quantities of material per DOT regulations. For category 2 material, these protections include requirements to maintain constant control and/or surveillance and, if applicable, requirements on carriers regarding package tracking systems and delivery signatures.

Findings involving category 1 radioactive material that result in the following are White.

- Failure to establish and maintain a movement control center (MCC) for the duration of the transit
- Failure to establish and maintain primary and secondary means of communication between the transport and the MCC prior to commencing transit
- Failure to establish active monitoring by a tracking system (e.g., telemetric position monitoring system or alternate) prior to commencing transit

The basis for this is that these failures significantly impact the ability of the MCC to assist the driver in the event of any security-related issue; resulting in an excessive reduction in the physical protection of the material. Isolated failures involving communications that occur after the transit has commenced and that do not result in complete loss of communications between the transport and the MCC are Green. Likewise, isolated failures of active monitoring by the tracking system that occur after the transit has commenced are Green; provided an acceptable secondary means of maintaining positive confirmation of the location, status and control over the shipment was provided for the duration of the transit. The basis for this is that collection of security provisions in Subpart D to Part 37 ensures a robust and layered approach to physical security that can absorb isolated failures with very low overall risk significance to material security.

A procedural deficiency, involving category 1 material, that results in a failure to respond to actual or attempted theft or diversion of category 1 material while in transit is White. The basis for this is that the failure on the part of the licensee could delay LLEA intervention such that radioactive material would be put at an excessive risk of theft or diversion. In these cases, the SDP for actual theft and diversion should be referenced as well, if applicable.

Failure to provide an accompanying driver, if required when transporting category 1 material, is White. The basis for this is that a single driver is not sufficient to provide adequate material security for periods greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration.

Findings involving category 2 radioactive material that result in the following are White:

- Failures establish and maintain the ability (or use carriers that maintain the ability) to identify when and where the package was last and when it should arrive at the next point of control for the duration of the transit (i.e., constant control and surveillance)
- Failure to use carriers that require authorized signature prior to releasing the package

The basis for this is that, for category 2 material, the physical protection in transit is primarily provided by the package tracking process; therefore, failures in establishing and maintaining this process results in an excessive reduction in material security.

Failure establish and maintain the ability (or use carriers that maintain the ability) to immediately communicate, when transporting category 2 material, is White. The basis for this is that this failure significantly impacts the ability of the licensee (or carrier) provide adequate material security because they would not be able to request response or assistance in the event of any security-related issue.

END

Attachment 1 – Revision History for IMC 0308, Attachment 3, Appendix D

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML042100267 06/25/04 CN 04-020	Initial Issue. The purpose of this change notice is solely to reformat the current IMC 0308 by dividing it into attachments and further into appendices. This new format will allow future basis document changes to be processed more efficiently.		
N/A	ML20346A502 CN 21-	<p>This issue is a major revision that was coupled with a revision of the corresponding SDP in IMC 0609, App D. Changes include reference to SRM-COMSECY-06-0023 as basis for findings involving substantial failures to implement effluent programs; deletion of the basis for White significance of radiological environmental monitoring program findings (to be consistent with the current SDP); addition of basis information in the transportation SDP and addition basis for dispositioning findings involving 10 CFR Part 37 at Part 50 licensees.</p> <p>Approval for this change was obtained from the Commission in accordance with Management Directive 8.13, "Reactor Oversight Process" January 31, 2020 through COMSECY-21-#### (ML#####) and SRM-COMSECY-21-#### (ML#####)</p> <p>Conducted public meetings as summarized in the following: ML21039A660 – October 21, 2020</p>	Inspector Seminar, TBD (training must be completed prior to issuance, per IMC 0040)	ML20346A522

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
		ML##### - February 25, 2021		

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