

1. Cross Cutting Issues

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<p>A. Define <i>DISCOVERY</i> as used in reporting requirements. Some situations appear to provide immediate discovery while some require a determination before discovery can be made.</p>	<p>It appears that this issue can be handled via clarification of the meaning of the word discovery. That is with perhaps examples there are a number of “types” of events or conditions to provide guidance on the determination of the point of discovery. This guidance could be used in a NUREG similar to 1022. The event driven occurrences are usually easier due to the self identification such as in a.1 but even the criteria in a.1 may not be readily identifiable until at least further analysis of a release is able to be accomplished with appropriate verification. This may also be true with regard to a.3 as a dose calculation or evaluation would need to take place to identify such an occurrence. While the source of the event (i.e., a release) may be able to be fixed in time of occurrence, the further evaluation of the dose ramifications of the release may take additional time to assess. Therefore the “discovery” would only be at the time when it has been determined by appropriate assessment that the criteria in paragraphs “a” or “b” have been exceeded. This issue does also have relations to item “B” below as these assessments need to be performed by qualified personnel many times with Health Physics or Chemical Hygiene capabilities. Front line employees and even line management usually do not have these capabilities. In the “b” criteria, a number of the criteria such as “b.1” and “b.5” also normally require</p>	

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	<p>assessment or evaluations that may not be short in duration in that there may be a good questioning attitude challenge to the accuracy or completeness of the original ISA or its underlying Hazards Analysis. In addition, deliberate reassessment or research into the concern or finding is necessary to complete the determination and “discovery” of the condition that may or may not be reportable. While there is an expectation that such an investigation be performed in a deliberate and controlled manner, it should not be the practice that the original ISA is considered to be defective until the determination is made. Most Corrective Action Programs have a means to control and manage these investigations to a final state at which time either the issue is determined to be reportable or not. That would be the time of “Discovery”</p>	
<p>B. Clarify the use of “qualified”/”cognizant” as used relative to <i>discovery</i> and determination of reportable events. Some situations are immediately evident to anyone; however, some require the use of other skilled or specially trained people.</p>	<p>Guidance should be established that the use of “qualified”/”cognizant” personnel is as defined by the Licensee’s policies and procedures.</p> <p>Each facility may have a different organizational structure and some conditions require the use of skilled or specially trained people to make such determinations.</p>	
<p>C. Better define “event” and “condition”</p>	<p>An “event” means (1) a situation characterized by an active adverse impact on equipment or personnel, readily obvious by human observation or instrumentation, such as a spill, over-pressurization, fire, etc., or (2) a radiological impact on personnel or the</p>	

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	<p>environment in excess of regulatory limits, such as an overexposure, a release of radioactive material above regulatory limits, or a loss of radiological material.</p> <p>A “condition” means an adverse impact on equipment or controls with the potential to cause harm to personnel or the environment, such as failure of a system to respond properly, discovery of a system that was not capable of performing its specified safety function (i.e., inoperable), etc.</p> <p>In the context of “unanalyzed condition”, this means that the physical condition or state of the facility is other than documented in the ISA and is such that the performance criteria of 70.61 are not met when using credited IROFS.</p>	
<p>D. Provide clarification as to what constitutes failure of a “70.61performance criteria” Particular attention should be given to 70.61 (d) which is out of context with (b) & (c) and does not define a particular performance/event situation.</p>	<p>Performance criteria for 70.61 (b) and (c) are clear and straight forward.</p> <p>Guidance for the performance criteria associated with the more procedural statements of 70.61 (d) and (e) should be established as follows:</p> <p><i>Processes are subcritical provided the parameters necessary to achieve criticality remain below those values established in the criticality safety evaluations, which include an approved margin of subcriticality stipulated in the facility license. However, each of the items used to maintain these controls or controlled</i></p>	

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	<p><i>parameters need not be listed as IROFS. Clarification of this issue may require a change to 10CFR 70.61 (e).</i></p> <p><i>The stipulation that controls and measures providing the protection against a criticality be preventative rather than mitigative is a prescriptive rather than a performance requirement.</i></p>	

2. 1 Hour Reporting Issues

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<p>A. Appx. A, (a) (2) should be consistent with 70.61 (b) (3) which applies the requirement only to those outside the controlled area.</p>	<p>70.61 (b) (3) states: “An intake of 30 mg or grater of uranium in soluble form by any individual located outside of the controlled area identified pursuant to paragraph (f) of this section.</p> <p>But the reporting requirements in Appendix A (a) (2) states: “An acute intake by an individual of 30 mg or greater of uranium in soluble form.”</p> <p>Industry recommends that this item either be deleted from Appendix A altogether as chemical exposures, other than this specific case with soluble U, are handled in (a) (3) and (b) (3).</p> <p>Or</p> <p>Revise Appendix A (a) (2) to state: “An acute intake of 30 mg or greater of uranium in soluble form by any individual located outside of the controlled area identified pursuant to paragraph (f) of 70.61.”</p>	

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<p>B. Appx. A, (a) (3) should be clarified to clearly denote that this refers to an actual intake/exposure and not a potential for an intake/exposure under some conditions that did not actually occur, i.e. exceeding a concentration does not equate to an actual intake/exposure unless the intake/exposure occurred. In addition there needs to be a clear parallel in the reporting guidance to the words in 70.61 (b) (4) with respect to the differences in (i) and (ii).</p>	<p>As the issue statement calls for clarification, this issue may be resolve via guidance and clarification in a NUREG 1022 type document. This clarification can draw upon the nexus between 70.61 b.4.i & ii. It needs to clearly state that an exposure has taken place exceeding the quantitative standards established by the licensee (and accepted by the NRC) with regards to 70.61b.4.i&ii. This is not to mean that there was a concentration that could have caused an exposure (although this issue may be reportable under the Appendix A.b criteria), but an actual dose accumulation by an individual. Note that this determination may need analysis or assessment for “discovery” as noted above in item 1.A.</p>	
<p>C. Regarding Appx. A, (a) (4) – Must the IROFS be explicit to the subject scenario or could they be IROFS documented in the ISA but associated with another scenario in the ISA? There are some mixed opinions but the general tendency is to say they do not have to be directly tied as long as they are identified and maintained as IROFS. Need clarity.</p>	<p>Guidance is needed to be consistent such that the IROFS do not have to be directly tied to the specific accident sequence as long as they are identified and maintained (including Management Measures) as IROFS. Need clarification.</p>	
<p>D. During calibrations and routine maintenance (licensed management measures) situations are found where IROFS may not be functioning precisely to the correct performance level. This should be clarified as a situation that does not fall under the reporting requirements of Appx. A, (a) (5) and does not require reporting. Wording/guidance similar to NUREG 1022, Section 3.2.2 should be incorporated.</p>	<p>Generally, a condition is reportable if surveillance testing (e.g., periodic inspections, tests, or calibrations, etc.) indicates that equipment was not capable of performing its specified safety functions <u>and</u> the performance requirements are not continued to be met.</p> <p>Reporting is not required if a condition exists solely of a case of a late surveillance test where the oversight is corrected, the test is performed, and the equipment is found to be</p>	

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	<p>capable of performing its specific safety functions <u>or</u> if the performance requirements continue to be met in spite of the late performance test.</p> <p>For the purpose of evaluating the reportability of a discrepancy found during surveillance testing refer to the following:</p> <p>(1) For testing that is conducted within the required time (i.e., the surveillance interval plus any allowed extension), it should be assumed that the discrepancy occurred at the time of its discovery unless there is firm evidence, based on a review of relevant information such as the equipment history and the cause of failure, to indicate that the discrepancy existed previously.</p> <p>(2) For testing that is conducted later than the required time, it should be assumed that the discrepancy occurred at the time the testing was required unless there is firm evidence to indicate that it occurred at a different time.</p> <p>The purpose for this approach is two fold. It rules our reporting of routine occurrences (i.e., occurrences where a timely surveillance test is performed, the results fall outside of acceptable limits, and the condition is corrected) unless there is firm evidence that the equipment was incapable of performing its specified safety function longer than allowed.</p>	

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	On the other hand, if the surveillance test is performed substantially late, and the equipment is not capable of performing its specified safety function, the occurrence is not routine. In this case the event is reportable unless there is firm evidence that the duration of the discrepancy was within allowed limits.	

3. 24 Hour Reporting Issues

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<p>A. Appx. A (b) (1) includes a statement “and with the failure to meet the performance requirements of 70.61”. It seems that the NRC is only applying the first part of the sentence and requiring that any one of those conditions require reporting without the conditional “and” statement being applied. The reasoning needs to be understood and possibly clarified.</p> <p>In addition, while reporting situations mentioned in Appx. A (b) (1) might rise to the level of significance of reporting in 24 hours. They more likely meet a significance of 30 days and intermediate consequence situations should only be corrected and reported during the annual update. These clarifications and reductions in burden should be considered.</p> <p>AICHe guidance indicates that it is unrealistic to document every possible accident scenario; however, it is reasonable for a licensee to have considered adequate and comprehensive scenarios such that accidents are generally bounded. Licensees speak of “bounding scenarios”. The guidance for this reporting requirement needs to factor in the guidance from AICHe and recognize the use of “bounding scenarios”. The term bounding scenarios should be defined/described in the guidance.</p>	<p>Enhance the guidance to assure that the conditional “AND” included in Appendix A (b) (1) is used in the evaluation of reporting stipulated in this section.</p> <p>No additional guidance is needed provided the conditional “AND” is used when evaluating situations related to Appendix A (b) (1).</p> <p>Guidance should provide, notwithstanding, the use of the word “ANY”, that consistent with AICHe methods and realistic hazards analysis, the licensee may consider bounding assumptions when determining if the facility is in an unanalyzed or improperly analyzed state. Bounding scenarios by definition cover the spectrum of accidents that can take place but do not necessarily describe every possible scenario in explicit detail.</p>	
<p>B. Appx. A (b) (5) needs to be clarified to apply only “when the performance requirements of 70.61 are no longer met”.</p>	<p>Industry recommends that Appendix a (b) (i) be changed from “Was dismissed due to its likelihood; or” to “Was dismissed due to its likelihood and whose associated unmitigated consequences would have exceeded those in part 70.61 (a) or (b).</p>	
<p>C. Appx. A (b) (5) (ii) – This appears to be redundant to (b) (1). If this is</p>	<p>The industry believes that App. A.b.5.ii is</p>	

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<p>the case it should be removed. If it is not redundant then guidance needs to be developed to indicate the difference and what is intended.</p>	<p>covered by App.A.b.1 and therefore is redundant. It is not clear as to why this paragraph was needed unless examples of cases where one could meet the criteria of 5.ii and not meet A.b.1. While redundancy is not in itself call for rulemaking for removal, at least guidance should be provided, and when convenient (when the rule may be changed for some other reason), this redundancy could be cleaned up.</p>	
<p>D. Appx. A (b) (3) – 70.61 (c) (4) (i) and this requirement are directly related. 70.61 (c) (4) (i) uses wording such as “irreversible, or other serious, long lasting health effects”. These are qualitative words that do not have universal definition and are open to numerous interpretations, therefore some clarification is needed to make sure reporting takes place correctly. Or should we develop a definition of “mild transient health effects” and use this definition as a demarcation boundary</p>	<p>The NRC and Industry should develop guidance documentation that includes definitions of the terms: irreversible, serious and long lasting health effects.</p> <p>This guidance should also define “mild transient health effects”.</p>	
<p>E. Appx. A (b) (4) appears to be redundant to 70.50 (b) (2) and Appx. A (b) (2). If this is the case it should be revised. If this is not the case then guidance is needed to clarify why it is different and what exactly is intended.</p> <p>In addition the requirement uses the phrase “or may have affected the intended safety function or availability or reliability of one or more items relied on for safety”. This statement should be removed because it is problematic in compliance space. It either has or has not affected and these hypothetical statements are confusing in regulatory space.</p>	<p>Although there are similarities with these requirements, there are subtle differences between them. For example, Appendix A(b)(4) is related to natural phenomena/external events that affect or potentially affect IROFS; Appendix A(b)(2) generically refers to loss or degradation of IROFS that results in failure to meet the performance criteria; and, 70.50(b)(2) refers to equipment required by regulation or the SNM license (e.g., required safety equipment that may not be designated as an IROFS like the CAAS, etc.).</p>	

4. Concurrent Reporting Issues

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<p>A. Appx. A (c) Industry basically agrees with this and supports it as “good practice”. The concern is that this can be carried too extreme without some additional guidance. It should apply to the licensed operations in terms of a compliance measurement.</p> <p>Many of the sites have any number of reporting requirements. For example the site sanitary sewer may have required reporting requirements that relate to the operation of the sewage treatment. These are far removed from the nuclear operations.</p> <p>Other sites may have multiple operations on the same site, some of which are indirectly related to their nuclear business but some that are totally independent of the nuclear business. These businesses may be required to make reports and reporting them to the NRC does not appear appropriate for a number of reasons.</p> <p>Supporting guidance is needed to make it clear the boundaries of required/compliance determining concurrent reporting that is required. Licensees obviously can be encouraged to be open with communications that may be mutually beneficial and in general that has been the industry practice.</p>	<p>Guidance should clarify that this applies only to concurrent reports directly related to the portion of the facilities directly related to the licensed activities.</p> <p>Situations not directly related to the licensed activities are not included as well as events on site from other “businesses” even though the licensee may elect to provide courtesy notifications.</p> <p>An example of a concurrent report would be a report to the State regarding the sanitary discharge permit for the sanitary plant serving the licensed activity.</p> <p>An example of a situation that would not be considered as concurrent reporting would be a State report for NO_x emission from a non-nuclear operation independent from the licensed facility but located on the same plant site.</p>	