DSS Open Item Categorization Process

Contents

1. INTRODUCTION

In the process of generating a safety evaluation (SE) on a submittal, the NRC technical review staff may encounter issues that require resolution beyond what is provided in the submittal. These issues are often left as open items in the SE, and represent issues the NRC staff has with specific statements in the submittal that preclude the submittal from being safely implemented as written. Sometimes, the issue is focused on a specific statement or set of statements contained in the submittal; sometimes, it is focused on a statement which the NRC staff believes should be in the submittal, but is not. In either case, these open items require additional information to be resolved, and are therefore often summarized as requests for additional information (RAIs). Once it is determined more information may be needed to resolve open times, RAIs will be issued in accordance with the Agency's formal process documented in LIC-500, "Topical Report Process" and LIC-101, "License Amendment Review Procedures."

Generally, the applicant believes that the submittal is complete and contains all necessary information for the NRC staff's review. Because of this, each open item represents a conflict between the information the NRC staff needs to come to a regulatory decision and the application. Resolving such conflicts requires effective communication between staff and management in addition, between NRC staff and the applicant. To aid communication in an effort to help resolve these conflicts, the NRC staff have developed a categorization process which provides important information about each Open Item.

2. CATEGORIES

This Open Item categorization process considers three important attributes for each open item, and assigns a level for each attribute:

1) The level of discrepancy - How much discrepancy is there between the NRC staff and the applicant on the open item?
2) The level of impact - If the open item is not resolved, what would the impact be on the safety evaluation?
3) The level of effort - What level of effort is the NRC staff expecting will be necessary to close the open item?

Each of these three attributes will be discussed below in detail below. Each attribute is separated into 5 different levels, and each Open Item is categorized by determining its level in each of its attributes. While it is recognized that different NRC staff may assign the same open item to different levels, the goal of categorization is not to normalize the NRC staff's response but to better communicate their concerns.

2.1.   Level of Discrepancy

This attribute quantifies the NRC staff's perception of the level of discrepancy between the staff and the applicant about the open item. While there may be complete disagreement, it is not always the case. In many instances, the staff may agree with the overall conclusion, but believe it is unsupported. Additionally, the staff may not completely disagree, but remain skeptical of the conclusion drawn. To help communicate the level of discrepancy, each open item should be scored using the following table.

Level of Discrepancy	Definition	Significance Score
1	The NRC staff understands the information presented in the application, but disagrees with that information.	1
2	The NRC staff understands the information presented in the application, but is unsure if the information is correct and does not believe the evidence provided justifies the conclusion presented in the submittal. The NRC staff remains skeptical. OR The NRC staff does **not** understand the information presented in the application, and believes the information is significant enough to warrant increased attention.	1
3	The NRC staff understands the information presented in the application, and agrees with the information, but believes the supporting evidence does not justify the conclusions presented.	0
4	The NRC staff does **not** understand the information presented in the application, but believes the information does not warrant increased attention.	0
5	The NRC staff is minimally concerned.	0

Levels one through four are mostly self-evident. Level five, a level for "minimal concern", is included because there may be circumstances where the NRC staff finds information to be necessary to reach a safety finding but do not believe that the information is very significant. Examples of open items in this level are editorial issues, misspellings, incorrect wording choices, undefined acronyms, and so on. These items, though not significant in and of themselves, may have a material impact on the meaning of specific statements in the submittal.

2.2. Level of Impact

This attribute quantifies the NRC staff's perception of the level of impact which would result if the open item were not resolved. For many topical reports, the safety evaluation may be completed without the resolution of every open item using conditions and limitations. The impact of the open item is based on the severity of the condition or limitation that the NRC staff feels would be needed if that item were not resolved. In some instances, failure to resolve an open item may result in a condition or limitation which would effectively disallow the use of the topical report, but those instances are rare. Often, an open item may be resolved by requiring a change to an area of the application, and in some cases, not resolving the open item would have almost no impact at all on the application. To help communicate the level of impact, each open item should be scored using the following table.

Level of Impact	Definition	Significance Score
1	The impact of the required condition or limitation is expected to be very large. The submittal would likely be denied or would be so limited that it would be effectively unusable.	1
2	The impact of the required condition or limitation is expected to be significant. The submittal would be useable, but significantly limited.	1
3	The impact of the required condition or limitation is expected to be moderate. The submittal would be useable, and only slightly limited.	0
4	The impact of the required condition or limitation is unknown, as the open item focuses on statements the NRC staff does not understand.	0
5	The impact of the required condition or limitation is expected to be minimal. The submittal would likely not be limited.	0

Again, levels one through four are mostly self-evident and level five is focused on editorial open items.

2.3.   Level of Effort

This attribute quantifies the NRC staff's perception of the applicant's level of effort needed to resolve the open item. In some instances, the open item may require a detailed report or a test program. In other instances the open item may only require confirmation of a fact that was not explicitly stated by the applicant. The level of effort therefore captures not only how much work is expected to be performed, but also how much information should be submitted to the NRC. This is likely the single most important attribute as it provides valuable details on the response expected from the applicant. To help communicate the expected level of effort, each open item should be scored using the following table.

Level of Effort	Definition	Significance Score
1	The open item will likely require a very large level of effort to resolve. Resolution of the open item is expected to require a very large amount of new work to be performed (e.g., on the order of weeks), or the submission of a very large amount of information (e.g., on the order of pages). Additionally, due to the extent of new information that must be submitted, it is possible that there may be additional open items on the newly submitted information.	1
2	The open item will likely require a significant level of effort to resolve. Resolution of the open item is expected to require a significant amount of new work to be performed (e.g., on the order of days), or the submission of a significant amount of information (e.g., on the order of pages).	0
3	The open item will likely require a moderate level of effort to resolve. Resolution of the open item is expected to require a moderate amount of new work to be performed (e.g., on the order of hours), or the submission of a moderate amount of information (e.g., on the order of paragraphs).	0
4	The open item will likely require a small level of effort to resolve. Resolution of the open item is expected to require a small amount of new work to be performed (e.g., on the order of an hour), or the submission of a small amount of information (e.g., on the order of sentences).	0
5	The open item will likely require a minimal level of effort to resolve. Resolution of the open item is expected to require a minimal amount of new work to be performed (e.g., on the order of minutes), or the submission of a minimal amount of information (e.g., on the order of a sentence).	0

3. SIGNIFICANCE SCORE

A significance score was also developed as a means to combine[1] the levels from each attribute into a single value which captured the open item's overall significance as either: high, moderate, or low. This information can be helpful to give an overview of all of the open items from a submittal, or in understanding the significance of one open item relative to the others in that submittal.

The total significance of any open item is the sum of that open item's significance score in each category. Thus, the highest significance score an open item can have is 3 and the lowest is 0. Based on that score, the open item's significance is assigned as given the table below.

Significance Score	Significance
≥ 2	**High**
1	**Moderate**
0	**Low**

These scores correspond to statements that approximately summarize each of the attributes. These statements are presented below. An open item has a high significance if two of the following statements are true, moderate significance if one of the following statements are true, or low significance otherwise.

- The NRC staff disagrees with statements in the topical or is skeptical about those statements.
- The impact of the resulting condition or limitation would substantially or significantly limit the submittal.
- The open item will likely require a very large level of effort to resolve.

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[1] This combination process involved weighting each level of each attribute with a different weight such that the scores could be directly added. This justification for this process is not discussed here, but involves the ordinal, interval, and ratio scales, and was developed using set theory.

4. APPLICATION

It is recommended that the categorization information for each Open Item be shared with the applicant when the Open Item is provided as a draft RAI, as this helps the applicant better understand the NRC staff's position. This information can also be shared with NRC leadership and other NRC staff members at any time to quickly give a visual summary of the state of the review. It is also recommended to only provide the level of effort with the final RAI, reserving the level of discrepancy and impact as NRC internal information.

The categorization information is provided in two tables. The first table, an example of which is given below in Table 1, provides the level of each Open Item in each attribute (discrepancy, impact, effort).

Table 1: Example of Open Item Categorization Summary

Open Item	Discrepancy	Impact	Effort	Significance Score	Significance
1	2	1	2	2	High
2	1	1	1	3	High
3	5	3	4	0	Low
4	1	1	1	3	High
5	2	3	3	1	Moderate
6	2	1	2	2	High
7	1	1	1	3	High
8	3	1	3	1	Moderate
9	3	1	3	1	Moderate
10	3	3	3	0	Low
11	3	3	2	0	Low
12	3	3	2	0	Low

The second table, an example of which is provided below in Table 2, proves a high-level summary of the number of Open Items and their significance.

Table 2: Example of Open Item Significance Summary

Level of Significance	Number of Open Items
High	5
Moderate	3
Low	4

5. CONCLUSION

The Open Item categorization process can be, and has been, very useful in better communicating issues to the applicant and NRC management. It provides clarity to the applicant, as they are able to better understand which Open Items the NRC staff finds the most significant and why, and provides details on the amount of information the NRC staff believes is necessary to resolve the Open Item. It also allows management to understand which Open Items are most significant and provides an overall state of the review based on the number of significant Open Items.