EXAMPLES OF LESS THAN SATISFACTORY FINDINGS OF PROGRAM PERFORMANCE FOR SEALED SOURCE AND DEVICE (SS&D) EVALUATION PROGRAMS

The effectiveness of a program is assessed through the evaluation of the criteria listed in Section III, Evaluation Criteria, of MD 5.6. These criteria are NOT intended to be exhaustive but provide a starting point for the IMPEP review team to evaluate this indicator. The review team should also take into consideration other relevant mitigating factors that may have an impact on the program's performance under this performance indicator. The review team should consider a less than satisfactory finding when the identified performance issue(s) is/are programmatic in nature, and not isolated to one aspect, case, individual, etc. as applicable.

This list is not all inclusive and will be maintained and updated in the IMPEP Toolbox on the state communications portal at https://scp.nrc.gov.

The following are examples of review findings that resulted (or could result) in a program being found "**satisfactory, but needs improvement**" for this indicator.

TECHNICAL STAFFING AND TRAINING

1. The team found that the program did not have sufficient qualified staff to complete the SS&D reviews in a timely manner. The program had only one reviewer qualified to conduct the sealed source and device evaluations, and a qualified manager to conduct the concurrence reviews. The one qualified reviewer was also responsible for other activities and only had a limited amount of time to spend on the reviews. As a result, the reviews were not processed in a timely manner, and were rushed resulting in errors in the reviews performed. However, no health and safety issues were identified with the reviews. This has cross jurisdictional health and safety implications.

2. During the review period, the program hired technical review staff that did not have the scientific or technical backgrounds that would equip them to receive technical training related to the review of SS&D. As a result, an evaluation for a device was issued without reviewing all of the technical features associated with the design and integrity of the device.

SEALED SOURCE DEVICE PROGRAM

1. The team found cases where the SS&D evaluations reviewed did not address the integrity of the products and important health and safety concerns with respect to thoroughness, completeness, consistency, clarity, technical quality, adherence to existing guidance in product evaluations. Specifically, the evaluations did not fully address deficiencies with prototype testing. As a result, sealed sources and devices containing radioactive material were approved that did not demonstrate the product would maintain its integrity during normal use and likely accident conditions. Making this determination is essential when deciding whether to approve a sealed source or device.

2. The program had 10 events of defects and incidents of devices subject to the SS&D program related to a particular irradiator. The program did not fully evaluate the root causes of all defects and incidents involving devices subject to the SS&D program. Specifically, the program did not evaluate three of the events related to the design defect

issue of the irradiator including a root cause evaluation. As a result, the staff did not determine whether the incidents were generic and would require either a design change to the device or a notification to users to make them aware of a potential safety concern. Additionally, the program was unable to demonstrate that they had a process to evaluate defects and incidents.

The following are examples of review findings that resulted (or could result) in a program being found "**unsatisfactory**" for this indicator.

TECHNICAL STAFFING AND TRAINING

1. The team found that the program did not have qualified staff to complete the SS&D reviews in a timely manner. The program had no qualified reviewers to conduct the sealed source and device evaluations, however evaluations were being performed. As a result, the reviews were not adequately performed and resulted in an integrity concern for one of the devices approved.

2. During the review period, the number of qualified SS&D reviewers has decreased from 10 down to 3. The program currently does not have enough qualified reviewers to handle the typical SS&D volume. As a result, actions have been completed without the concurrence review of the technical reviewer's evaluation.

3. The program's SS&D training program does not meet most of the criteria IMC 1248 and NMSS procedure SA-103 for SS&D reviewers. The training program was deficient/did not fully address directed review of selected SS&D case work, regulatory requirements, and industry codes and standards to meet the criteria of IMC 1248.

SEALED SOURCE DEVICE PROGRAM

1. The team found in most of the cases reviewed, that the SS&D evaluations did not address the integrity of the products and important health and safety concerns with respect to thoroughness, completeness, consistency, clarity, technical quality, adherence to existing guidance in product evaluations. Specifically, evaluations did not fully address deficiencies with prototype testing. As a result, sealed sources and devices containing radioactive material were approved that did not demonstrate the product would maintain its integrity during normal use and likely accident conditions. Making this determination is essential when deciding whether to approve a sealed source or device.

2. The program had 10 events of defects and incidents of devices subject to the SS&D program related to a particular irradiator design. The program did not fully evaluate the root causes of all defects and incidents involving devices subject to the SS&D program. Specifically, the program did not evaluate nine of the events related to the design defect issue of the irradiator including a root cause analysis. As a result, sealed sources and devices containing radioactive material were approved that did not demonstrate the product would maintain its integrity during normal use and likely accident conditions. Making this determination is essential when deciding whether to approve a sealed source or device. Additionally, the program was unable to demonstrate that they had a process to evaluate defects and incidents.