EXAMPLES OF LESS THAN SATISFACTORY FINDINGS OF PROGRAM PERFORMANCE FOR TECHNICAL QUALITY OF INSPECTIONS

The effectiveness of a Program is assessed through the evaluation of the criteria listed in Section III, Evaluation Criteria, of Management Directive (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 fully 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 website.

A finding of "satisfactory, but needs improvement" should be considered when more than a few or a small number of the cases or areas reviewed involve performance issues/deficiencies in high risk-significant regulatory areas, but not to such an extent that the finding would be considered unsatisfactory.

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

1. During accompaniments, inspectors missed identifying violations and were not knowledgeable of the regulations or license conditions regarding these violations. The violations had potential health, safety, and/or security consequences, such as the following:

    - Failure to perform an annual program review
    - Transporting the shipping paper in the glove box
    - Performing leak tests annually instead of every six months
    - Failure to perform a linearity check for a dose calibrator
    - Failure to perform a physical inventory of well logging sources
    - Failure to secure a portable gauge with two independent physical controls when not under the direct control of the licensee.

2. Inspection casework files indicated that there were previously cited violations which dealt with health, safety, and/or security concerns. However, the inspection documentation did not address those previously cited violations, and interviews with inspectors indicated that the previously cited items were not reviewed during the most recent inspections.

3. Casework files indicated that the documentation was not complete or was lacking required elements (e.g. security was not reviewed during a blood irradiator inspection; a high dose rate (HDR) system was not inspected at a broad scope medical inspection, transportation was not reviewed at a pharmacy). Interviews with inspectors confirmed that those elements were not reviewed during the inspections. Program management review of inspection documentation did not identify this gap.

4. In more than a few of the medical inspection casework reviewed, the Program's inspectors did not examine written directives for therapeutic doses to determine whether a medical event occurred for licensee's who are authorized for activities under 10 CFR 35.300, 35.400, 35.600, and 35.1000.

5. During accompanied inspections, the inspectors did not directly observe work activities or interview workers present on site. The inspectors relied solely on a review of records and speaking with the licensee's radiation safety officer, contrary to the Program's inspection procedures which state that the inspector's evaluation of a licensee's program shall be based on direct observation of work activities, interviews with workers, demonstrations by workers performing licensed activities, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. As a result, the inspectors did not identify violations.

6. Supervisory accompaniments were not performed by qualified individuals in two of the four years during the review period, and inspector accompaniments by the IMPEP team member identified performance concerns.

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

1. During most of the inspection accompaniments, inspectors missed identifying violations and were not knowledgeable of the regulations or license conditions regarding these violations. The violations had potential significant health, safety, and/or security consequences, such as the following:
    - Operating a permanent radiography cell without an operating audible/visible alarm.
    - Failure to perform a spot-check for a gamma stereotactic radiosurgery unit before the first use of the day.
    - Failure to secure a radiographic exposure device at a temporary jobsite with two tangible barriers when not under the direct control of the licensee.
    - Failure to perform thyroid bioassays for a scientist who weekly performed 20 mCi iodinations with I-125.
    - Failure to assess a skin contamination event at a Positron Emission Tomography (PET) hot cell.

2. A majority of the casework files reviewed were inspections of medical facilities with administrations requiring written directives. For most casework files reviewed, the documentation indicated that administrations of radioactive materials were in excess of the written directive by more than 20 percent; however, this was not identified as a violation in any of the files. Interviews with Program staff indicated that they were unaware of the relevant regulation and the management review was inadequate to identify the discrepancy.

3. The reviewer determined that the Program was not evaluating compliance with 10 CFR Part 37 during the initial inspections for most of their new licensees possessing Category 1 and 2 quantities of radioactive material. The Program's procedures did not address initial security inspections and management review of the inspection reports failed to identify this issue.

4. During the accompaniments, the Program's inspectors did not review written directives, the determination of the prescribed dose, the validation of the prescribed dose compared to the administered dose, or the determination of a medical event. A review of selected medical inspection documentation showed a lack of review of written directives and medical events. Program management review of inspection documentation and supervisory accompaniments also did not identify this gap. As a result, the Program did not identify a medical event.

5. During most inspection accompaniments for licensees who possess Category 1 and 2 quantities of radioactive materials, the inspectors failed to verify that select alarm systems were functioning as designed. The inspectors did not have licensee personnel verify the security systems' functionality. The inspector did not verify that the licensee regularly tested the alarms. As a result, the Program did not identify a non-functioning security system.

6. Most of the casework reviewed for licensees who possess Category 1 and 2 quantities of radioactive material demonstrated that the inspectors did not review the licensee's access authorization program. The inspectors noted in their report that new personnel were hired since the last inspection and were granted unescorted access to the security zone. During interviews, the inspectors confirmed that they did not review the access authorization process and relied solely on the licensee's conclusion for trustworthiness and reliability.

7. Based on interviews with the Program's inspectors and a review of inspection casework, most of the inspections with licensees who had previously identified non-compliances were not evaluated by the inspectors. Inspectors did not evaluate the effectiveness of the licensee's corrective actions to prevent recurrence. The Program's procedure was missing verification of previous violations. As a result, the review team identified multiple occurrences of repeat violations and the occurrence of an overexposure directly related to the licensee's failure to implement effective corrective actions.

8. Supervisory accompaniments were not performed by qualified individuals for most of the inspectors during the review period and inspector accompaniments by the IMPEP team member identified performance concerns during most of the inspector accompaniments that were determined to be safety significant.