

# NRC INSPECTION MANUAL

FCSS

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## MANUAL CHAPTER FCOP-SDP

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### FUEL CYCLE SIGNIFICANCE DETERMINATION PROCESS

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## FCOP-SDP-01 PURPOSE

The Fuel Cycle Significance Determination Process (FCSDP) uses risk insights, where appropriate, to help the Nuclear Regulatory Commission (NRC) inspectors and staff determine the safety or security significance of inspection findings. The safety or security significance of findings is used to assess a licensee's level of safety performance, and to determine the level of NRC engagement with the licensee. Each FCSDP supports a cornerstone associated with the strategic performance areas as defined in Inspection Manual Chapter (IMC)-FCOP-BASIS DOCUMENT, "Fuel Cycle Oversight Process (FCOP) Basis Document." The FCSDP determinations for inspection findings are used to assessing licensee performance in accordance with guidance provided in IMC-FCOP-ASSESSMENT, "Fuel Cycle Facility Assessment Program."

The staff should complete FCSDP evaluations in a timely manner in order to promptly direct NRC resources to those licensees with weaker performance. However, for certain findings where circumstance may require delay in the issuance of final significance determination, the guidance of this inspection manual chapter should be implemented.

## FCOP-SDP-02 OBJECTIVES

02.01 To characterize the safety or security significance of inspection findings for the NRC Fuel Cycle Oversight Process (FCOP), using best available risk insights.

02.02 To provide all stakeholders an objective and common framework for communicating the potential safety or security significance of inspection findings.

02.03 To provide a basis for timely assessment and/or enforcement actions associated with an inspection finding.

## FCOP-SDP-03 APPLICABILITY

03.01 The FCSDPs described in the Appendices of this Manual Chapter are applicable to inspection issues identified through the implementation of the NRC inspection program described in IMC 2600. Violations without an associated performance deficiency will not be subject to these FCSDPs. Issues that do not represent deficient licensee performance are not subject to this guidance but may need to be addressed by other NRC processes (e.g., Backfit Rule, Generic Safety Issues, Rule-making).

03.02 Nothing in this guidance relieves any licensee from fully complying with Technical Safety Requirements (TSR), License Conditions, License Applications, licensing basis commitments, or other applicable regulatory requirements. Continued compliance with regulatory requirements maintains the requisite defense-in-depth and safety margins necessary to achieve adequate protection of public health and safety.

03.03 The risk significance of significant Fuel Cycle events must be assessed by NRC risk analysts in accordance with Management Directive (MD) 8.3, "NRC Incident Investigation Program." Although the risk evaluation may provide useful risk insights to inspectors for event response or follow-up, an MD 8.3 evaluation is not used to determine the risk significance of a licensee performance deficiency being processed under the FCSDP. The performance deficiencies associated with an actual Fuel Cycle event should be dispositioned using the FCSDP in the same fashion as all other performance deficiencies.

03.04 Enforcement associated with violations of regulatory requirements will continue to be processed in accordance with the NRC Enforcement Policy and any applicable Enforcement Guidance Memoranda (EGMs). Minor violations, as defined by the enforcement policy and the FCSDP, are not required to be closed out through followup inspection.

#### FCOP-SDP-04 DEFINITIONS

Applicable definitions are located in IMC 0616, "Fuel Cycle Safety and Safeguards Inspection Reports."

#### FCOP-SDP-05 RESPONSIBILITIES AND AUTHORITIES

All NRC inspectors are required to assess the significance of inspection findings in accordance with the guidance provided in this Manual Chapter. General and specific responsibilities are listed below.

##### 05.01 Director, Office of Nuclear Material Safety and Safeguards (NMSS).

- a. Provide overall program direction for the FCOP.
- b. Develop and direct the implementation of policies, programs, and procedures for regional application of the FCSDP in the evaluation of findings and issues associated with the FCOP.
- c. Assess the effectiveness, uniformity, and completeness of regional implementation of the FCSDP.

##### 05.02 Director, Division of Fuel Cycle Safety and Safeguards.

- a. Approve all FCSDPs and direct the development of future FCSDPs and improvements through periodic revisions based on new risk insights and feedback from users.
- b. Provide oversight and representatives as necessary to support the Significance and Enforcement Review Panel (SERP) in order to ensure consistent and timely application of the process.

- c. Recommends improvements to all FCSDPs using a probabilistic risk framework and authorizes changes to facility-specific risk insight information used by the FCSDP, based on new risk insights and feedback from users.
- d. Provide oversight and representatives as necessary to support the SERP in order to ensure consistent and timely application of the process.

05.03 Regional Administrator, Region 2.

- a. Provide program direction for management and implementation of the FCSDP to activities performed by the Regional Office.
- b. Maintain overall responsibility for, and apply regional resources as necessary, to determine the significance of specific inspection findings in a timely manner, using best available information consistent with the FCSDP timeliness goal.

05.04 Director, Division of Fuel Facility Inspection, Region 2.

- a. Manages the implementation of the Significance Determination Process for inspection findings assigned to the regional office.
- b. Coordinates with FCSS to obtain specialized assessment expertise, as necessary to support the significance determination of inspection findings.
- c. Assists in the development and maintenance of the significance determination process for fuel cycle inspection program.
- d. Ensures that branch chiefs assign inspectors who are appropriately trained and have the necessary knowledge and skills to successfully implement the significance determination process.
- e. Insures that inspection findings are dispositioned in a timely manner.

05.05 Director, Nuclear Security Incident Response.

- a. Provide overall program direction for the security FCOP.
- b. Assist in the development and implementation of policies, programs, and procedures for regional application of the security FCSDP in the evaluation of findings and issues associated with the security FCOP.

05.04 Director, Office of Enforcement.

- a. Ensure consistent application of the enforcement process to violations of NRC regulations with the appropriate focus on the significance of the finding.
- b. Provide representatives as necessary to support the SERP in order to ensure consistent application of the enforcement process.

- c. Coordinate with NMSS, Region 2, and NSIR, as appropriate, when revising agency documents used for communicating to the licensee about apparent violations and final determinations associated with the FCOP.

05.05 Director, Office of Nuclear Regulatory Research.

- a. Provide support in the development and refinement of the FCSDPs, which use risk insights from research activities, based on user need requests.
- b. Provide representatives, when requested, to support the SERP.

05.07 NRC Risk Analysts.

- a. Support NRC objectives related to the utilization of risk insights in the Fuel Cycle inspection program in the form of a risk-informed FCOP, and in the use of the FCSDP.
- b. Support the FCOP and its specific objectives as presented in Attachment 5 to this Manual Chapter.

FCOP-SDP-06 BACKGROUND

Background for the development of the significance determination process for fuel cycle facilities can be found in IMC-FCOP-BASIS DOCUMENT, "Fuel Cycle Oversight Process Basis Document."

FCOP-SDP-07 FCSDP AND ENFORCEMENT REVIEW PANEL PROCEDURES

The processing of an issue through the FCSDP will follow the general outline provided in Figure 1, FCSDP General Flowpath.

07.01 Initial Evaluation Of Inspection Results.

All operating Fuel Cycle inspection findings are developed as a result of the implementation of the NRC Fuel Cycle inspection program described in IMC 2600.

The evaluation of inspection results begins with a determination of if an issue of concern will be documented for consideration in the FCOP assessment process. The process for the successive evaluation of inspection results is described in the following sections. Detailed instructions are provided in Attachments 1 through 5, and in the Appendices to this Manual Chapter. Guidance for documenting issues is provided in IMC-FCOP-REPORTS, "Fuel Cycle Safety and Safeguards Inspection Reports."



#### 07.02 Determination of the Existence of a Performance Deficiency.

Evaluate the issue of concern using Attachment 1, "FCSDP Determination of Finding of Greater than Minor Significance." Attachment 1 provides guidance to evaluate the following:

- a. Determine if an issue of concern is a performance deficiency. It must be a performance deficiency before it can be considered a finding.
- b. If the issue of concern is a performance deficiency, it is then evaluated to determine if it should be dispositioned under the enforcement process. Findings that meet the criteria for enforcement are evaluated in accordance with the Enforcement Policy to determine the significance (severity level).
- c. If the issue of concern is not a performance deficiency but is associated with a violation, it must be evaluated under the guidance of the Enforcement Manual.
- d. If additional information is needed to determine if the issue of concern is a performance deficiency then the issue is an unresolved item.

#### 07.03 Evaluate for More than Minor.

Attachment 1 also evaluates the deficiency to determine if it is below the documentation threshold for the assessment process, and therefore should be a Minor Issue. A performance deficiency must be more than minor to be considered a finding. For FCOP, examples of minor performance deficiencies are provided in Attachment 2 of this Manual Chapter. If the performance deficiency is sufficiently similar to a minor example, then the performance deficiency is minor. If the performance deficiency is minor, it is not a finding, will not be considered in the FCOP assessment process, and in most cases will not be documented.

For enforcement, examples of minor violations are provided in the supplements of the Enforcement Policy.

After the evaluations, Attachment 1 will direct the inspector to continue the FCSDP by going to the appropriate Appendix. The appropriate Appendix will process the finding through the Phase 1, initial screening, and Phase 2, if required, for the preliminary final significance determination.

#### 07.04 Screen for Significance (Color or Severity Level).

Findings are generally discussed with licensee representatives during the inspection process and are formally presented at an exit meeting with licensee management at the conclusion of the inspection period. The significance determination for each finding will generally take place in parallel with the development of the facts surrounding the finding but may not be complete at the time of the exit meeting. Documentation of findings, including details required to support the results of the FCSDP, will be done in accordance with guidance provided in IMC-FCOP-REPORTS, "Fuel Cycle Safety and Safeguards Inspection Reports."

All findings (licensee-identified, NRC-identified or self-revealed) must be screened for significance to determine if they are potentially significant (greater than Green or SLIII or above). Until the significance has been finalized, it is appropriate to state that the significance of the item is To Be Determined (TBD).

07.05 Characterization of Significance of Findings. Initial significance determination is normally performed by the inspector using the Phase 1 worksheet that is part of each, Cornerstone specific guidance found in Appendices A thru G.

- a. If the determination result is Green, then this would represent a final determination and will be characterized as Green at the exit meeting and in the inspection report.
- b. If the determination result is potentially greater than Green, then it will receive additional review(s) by the regional staff. The inspectors and regional staff should obtain from the licensee any readily available information in a timely manner to best inform the staff's preliminary significance determination, taking into account FCSDP timeliness goals as described in Section 07.10 of this Manual Chapter. The inspector should continue to evaluate the finding using the Cornerstone specific Significance Process defined in the appropriate Appendix. Potentially greater than Green findings evaluated using Appendix A, which have a more quantitative basis, are referred to the agency risk analyst for evaluation under Phase 2 of the FCSDP, in accordance with Part 2, "FCSDP Phase 2 Determination" of Appendix A.

All findings with a potential significance of White, Yellow, Red, or greater than Green will be reviewed by the SERP as described in Attachment 3 of this Manual Chapter. The result of the SERP review represents the staff's preliminary safety or security significance assessment. However, when a potential White, Yellow, or Red finding is determined to be Green by the SERP, this will represent a final determination and will be characterized as such in the inspection report.

If the staff's significance determination of a finding is not complete at the time of issuance of the inspection report, and not reviewed by the SERP, then the finding will be characterized in the inspection report as TBD. No inspection finding should be described by a color other than Green or greater than Green in official NRC correspondence unless the SERP has reviewed it.

07.06 Obtaining Licensee Perspectives on Initial Characterization of Significance. If the preliminary significance assessment is White, Yellow, Red, or greater than Green, then the licensee will be given the opportunity to formally present any further information or perspective, or to accept the staff's decision. This opportunity will be offered in the cover letter of the inspection report or the Preliminary Determination letter and will allow the licensee to request a public Regulatory Conference, or provide a written response on the docket, to present facts and their evaluation of significance. Security related matters will normally not be public, either at a conference or in correspondence.

The preliminary significance determination letter must clearly state, with sufficient detail, the staff's basis for their decision to enable the licensee to understand and provide further information to assist the staff in making the best informed final significance determination.

In the case of a greater than Green finding, the staff should request from the licensee additional information needed to assist the staff in making its final determination. In all cases, the correspondence to the licensee should include a date for the licensee to provide the information requested to support FCSDP timeliness.

It is expected but not required that the licensee provide on the docket, prior to the Regulatory Conference, any information considered applicable to the finding(s). Any non-sensitive information provided by the licensee during the Regulatory Conference will be made public.

07.07 Finalization of the Staff's Significance Determination. If the licensee accepts the staff's preliminary determination in a written response, then the staff will issue it as the final determination of significance. If the licensee provides further information on the docket by mail or during a Regulatory Conference, then the regional staff with NRC headquarters staff participation will make its final significance determination after evaluating this information. If the staff, after consideration of the licensee's additional information, determines that the initial characterization of significance should not change, the final determination of significance will be issued. The final significance determination will be a color (Green, White, Yellow, or Red) which corresponds to the safety significance of the finding as determined by the appropriate analyses. After considering the licensee's additional information, if the staff determines that a change in the initial characterization of significance is warranted or should be considered, then the SERP will schedule a review in accordance with the guidelines in this Manual Chapter.

In the case where the staff has issued a preliminary significance determination of greater than Green and the licensee has not or cannot provide sufficient information to better inform the staff's significance determination in a reasonable period of time, then the staff should determine final significance using its best objective rationale, and document this rationale fully in a letter to the licensee. This is expected to be rare and should conform to all FCSDP procedural requirements.

When the SERP agrees on the final determination of significance, the licensee will be informed of the final color of the finding in a letter. Enforcement actions stemming from the finding, if applicable, will generally be forwarded at that time, and the licensee will be informed of the FCSDP appeal process described in Attachment 4 of this Manual Chapter.

07.08 Analyze for Cross-Cutting Aspects.

All NRC-identified and self-revealing findings and all licensee-identified potentially greater than green findings shall be assessed for potential cross-cutting aspects. This includes findings assessed using SDPs or through enforcement. Specific guidance for this evaluation can be found in IMC-FCOP-ASSESSMENT, "Fuel Cycle Facility Assessment Program."

07.09 Screening for Applicable Enforcement Action.

This screen determines how a finding or a violation will be categorized (i.e., FIN, NCV, discretion, etc.) and whether a violation associated with a finding should be cited or non-cited as discussed in the NRC Enforcement Policy.

- a. For findings assessed in the SDP:
1. If the finding did not involve a violation of requirements, then the finding is a FIN or TBD depending on its significance. There is no enforcement action. Document the finding in accordance with IMC-FCOP-REPORTS, "Fuel Cycle Safety and Safeguards Inspection Reports"; or
  2. If the finding involves a violation and the significance is Green, then the violation must be evaluated to determine if it should be cited or non-cited in accordance with the NRC Enforcement Policy. The inspector must evaluate the immediate corrective actions performed by the licensee, and determine whether the licensee entered the issue into the corrective action program to address recurrence. (Note: For the guidance on "to address recurrence" see the NRC Enforcement Policy and Enforcement Manual.); or
  3. If the finding involves a violation and the significance of the finding is potentially greater than Green, then the finding is an Apparent Violation (AV). The final significance and appropriate enforcement action will be determined in accordance with this Chapter and/or the Enforcement Policy. Document the finding in accordance with IMC-FCOP-REPORTS, "Fuel Cycle Safety and Safeguards Inspection Reports."
- b. For findings with enforcement:
1. If the finding involves a Severity Level IV violation, then the violation must be evaluated to determine if it should be cited or non-cited in accordance with the NRC Enforcement Policy. The inspector must evaluate the immediate corrective actions performed by the licensee to determine whether the licensee entered the issue into the corrective action program to address recurrence, and whether the violation was repetitive. (Note: For the guidance on "to address recurrence" see the NRC Enforcement Policy and Enforcement Manual.); or
  2. If the finding involves a potentially greater than Severity Level IV violation, then the finding is an AV. Document the finding in accordance with IMC-FCOP-REPORTS, "Fuel Cycle Safety and Safeguards Inspection Reports."
- c. For violations with no performance deficiencies:
1. Work with the Office of Enforcement through the Regional Enforcement Coordinator to disposition these violations. Document the violation in accordance with IMC-FCOP-REPORTS, "Fuel Cycle Safety and Safeguards Inspection Reports."

07.11 FCSDP Timeliness. The Agency's goal for FCSDP timeliness is that all final significance determinations be completed within 90 days from the issue date of the first official correspondence that described the finding or documented the need for further review to determine significance. All attempts should be made to meet this goal, however, it is recognized that certain issues, due to their complexity, may result in occasions where the goal is exceeded.

The timeliness criteria below represent the maximum time approximated for each process milestone in order for the Agency to meet the 90 day goal.

- T<sub>0</sub> - The issue date of the first official correspondence describing the finding, either in an inspection report and/or Preliminary Determination letter
- T<sub>30</sub> - Latest date to issue the Preliminary Determination letter
- T<sub>70</sub> - Latest date for completing the Regulatory Conference with licensee
- T<sub>90</sub> - Final Determination letter issued

The Agency successfully completing the FCSDP process within 90 days is dependent upon timely completion of a public Regulatory Conference or receipt of a written response. The timeliness criterion below represents the maximum time approximated for each process milestone for the licensee to establish the Regulatory Conference within the 90 day goal. This timeliness goal is developed in detail in Attachment 3 to this Manual Chapter.

- T<sub>L0</sub> - Issue date of the Preliminary Determination letter issued in an inspection report cover letter or separate correspondence
- T<sub>L10</sub> - Licensee responds no later than 10 days from the issue date of the notification of the Preliminary Determination
- T<sub>L40</sub> - Regulatory Conference completed or licensee's written response received by NRC no later than 40 days from the issue date of the notification of the Preliminary Determination

#### 07.12 Exceptions to the Timeliness Goal.

- a. Experience has shown that inspection findings that may take longer than the 90 day goal to assess for significance meet one or more of the following criteria:
  - 1. Findings are of such technical complexity that existing FCSDP evaluation tools are not readily adaptable to the issue; and/or the region does not have the expertise or resources to risk inform the finding.
  - 2. Findings have potentially high safety significance (i.e., Yellow or Red) that should be carefully examined for potential impact on facility safety and subsequent NRC action.

In these cases, additional time may be necessary to complete a preliminary and/or a final determination of safety significance. However, findings for which the 90 day goal is not met, including findings where the limit was extended, will continue to negatively impact the timeliness goal and associated FCSDP timeliness metrics (Later).

- b. Some findings may involve a formal Office of Investigation (OI) or Department of Justice (DOJ) investigation. When an inspection finding involves a formal OI/DOJ investigation and it is known that the results of the investigation will not impact further evaluation of the finding's significance and/or follow-up inspection, then the finding should be resolved using the normal FCSDP process. If the OI/DOJ investigation does impact the timely resolution of the finding, then the guidance for a planning SERP should be implemented.

07.13 Planning SERP. For findings considered by the Region to meet the timeliness criteria of Section 07.12a, a Planning SERP, convened early in the process, will reach consensus on the scope of evaluation to be performed, the schedule on which the evaluation will be completed, and who will perform the evaluation. This Planning SERP is convened at the discretion of the applicable regional sponsor of the finding with cooperation of the Head Quarters (HQ) staff.

Before presenting to the Planning SERP, the regional sponsor should coordinate with HQ staff on determining the scope for the evaluation (e.g., simplified Phase 2, or detailed Phase 2 FCSDP), the need for additional information and expertise, and the estimated time necessary to obtain an acceptable risk informed preliminary finding.

It is expected that no assessments will be delayed beyond 90 days. However, if the SERP agrees that specific circumstances will delay the final characterization beyond 90 days, the Regional Administrator and the NMSS Office Director must be notified.

If the Planning SERP reaches consensus that additional time is warranted beyond 90 days, a schedule must be developed for the key milestones above. Findings requiring greater than the 90 day goal will continue to have a negative impact on the FCSDP timeliness metrics. (Later)

#### FCOP-SDP-08 PROCESS FOR LICENSEE APPEAL OF A STAFF FCSDP DETERMINATION

If a licensee disagrees with the staff's final determination of significance, the licensee may appeal the determination to the appropriate NRC Regional Administrator as described in Attachment 4 of this Manual Chapter. Any such review must meet the requirements stated in the Prerequisites and Limitations sections of Attachment 4 to merit further staff consideration. Specifically, the licensee must have opted for an opportunity to present additional information to the staff either by meeting with regional management at a Regulatory Conference or by submitting additional information in writing on the docket.

## FCOP-SDP-09 USING THE FCSDP TO DETERMINE THE SIGNIFICANCE OF INSPECTION FINDINGS THAT ARE NOT VIOLATIONS OF THE LICENSING OR DESIGN BASIS

The staff's use of the FCSDP to determine the significance of the result or consequence of a licensee performance deficiency will be made regardless of whether the result or consequence constitutes a violation of a licensee's licensing or design basis or any other regulatory requirement or commitment. Agency follow-up of such findings, if determined to be significant, will be handled in accordance with the backfit rules of 10 CFR 70.76 and 73.76 as appropriate.

## FCOP-SDP-10 FCSDP DEVELOPMENT AND FEEDBACK PROCESS

The development of a new FCSDP or significant modification of an existing FCSDP should follow the general process used for original FCSDP development. This process should include the following general steps:

- a. The draft of the FCSDP or the modification is subjected to internal NRC stakeholder review, including NRC regional input. Early external stakeholder input may also be solicited through public meetings, if appropriate.
- b. A feasibility review is performed by the NRC staff to assess the adequacy of the proposed FCSDP or changes. This review should specifically involve regional representation and should test the FCSDP with real (preferred) or hypothetical inspection finding examples. This review should determine if the proposed FCSDP or change is ready to be issued for public comment and/or for initial evaluation through field use by regional inspectors.
- c. Upon reconciliation of public comments and initial user feedback, the FCSDP or change is issued as a revision to this Manual Chapter.
- d. Appropriate training will be provided to the NRC inspection staff.

IMC XXXX "Fuel Cycle Oversight Process Feedback Program," describes in detail the feedback process and feedback form used by the Office of NMSS, to document problems, concerns, or difficulties encountered during implementation of the NRC's FCOP.

END

## Figure 1, FCSDP General Flowpath

Supplementary Documents Listing (documents to be issued separately):

### Attachments:

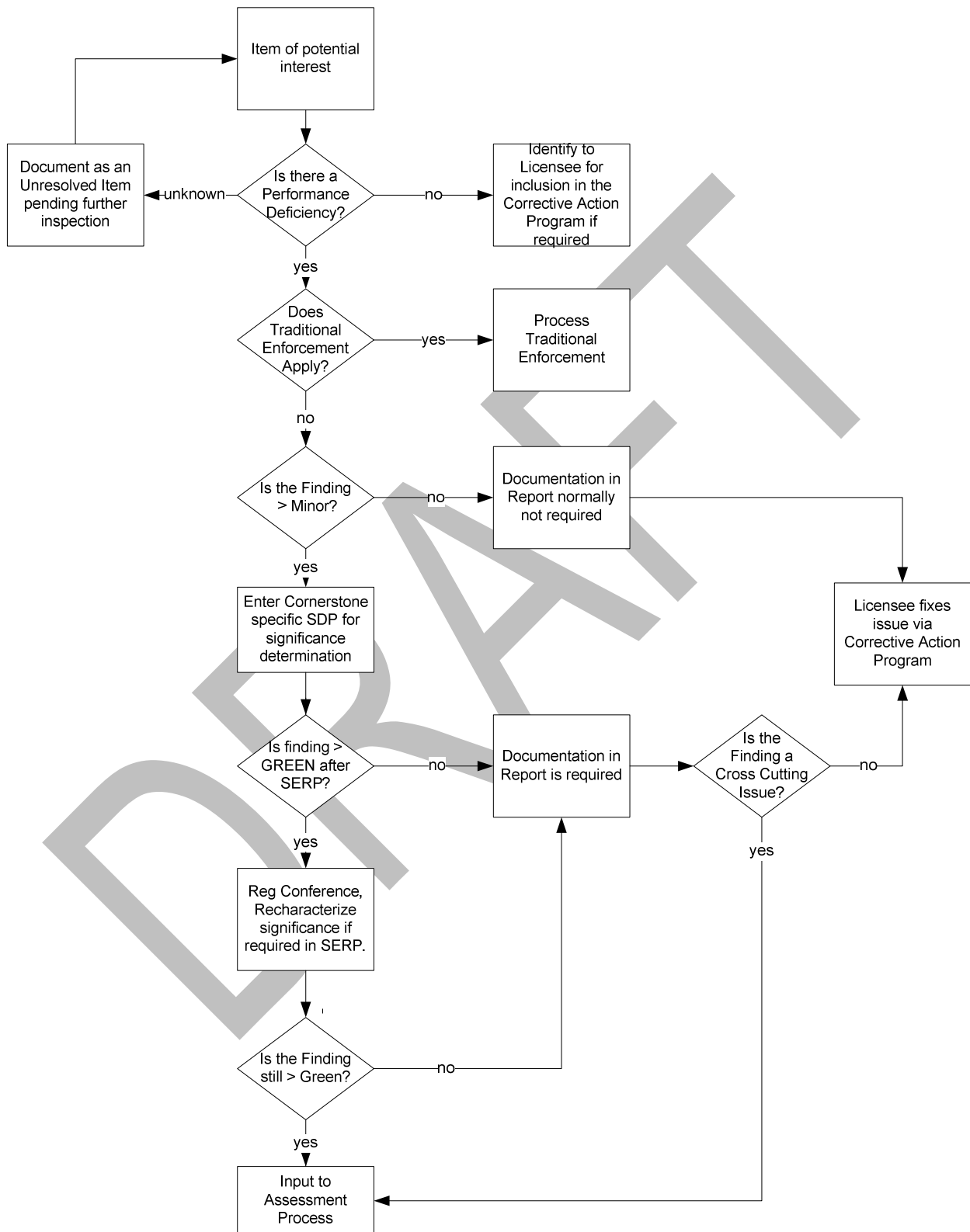
1. FCSDP Determination of Finding of Greater than Minor Significance.
2. FCSDP Minor Issue Examples
3. FCSDP Significance and Enforcement Review Panel Process
4. FCSDP Process for Appealing NRC Characterization of Inspection Findings (SDP Appeal Process)
5. Fuel Cycle Risk Analyst Support Expectations

### Appendices:

- A. Chemical Process Safety, Criticality Safety, Public Radiation Safety, Occupational Radiation Safety
  - Part 1 FCSDP Phase 1 Screening, Initial Characterization of Findings
  - Part 2 FCSDP Phase 2 Determination
- B. Emergency Preparedness
- C. Material Control and Accounting (MC&A)
- D. Information Security
- E. Physical Security Significance and Enforcement Review Panel Process
- F. (Reserved)
- G. Occupational Radiation Safety FCSDP (For 10CFR Part 20 findings)
- M (Reserved)



Figure 1  
 FCSDP General Flowpath



Revision History IMC XXXX

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number

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