IRRS UNITED STATES 2010

Question and Response Report

for:

Module 08: Enforcement

Question No: 161	Module 08: Enforcement
Question	
What is the legal basis for enforcement?	
D.	
Response	

The U.S. Nuclear Regulatory Commission (NRC) may issue orders to impose requirements pursuant to Section 161 of the Atomic Energy Act of 1954, as amended (AEA). Section 161.b of the AEA gives the Commission the power to establish by rule, regulation, or order such requirements as necessary to promote the common defense and security, to protect health, or to minimize danger to life or property. Section 161.i gives the Commission the power to prescribe regulations necessary to protect restricted data, to guard against the loss or diversion of special nuclear material, to govern activities authorized by the AEA, and to ensure sufficient funds will be available for decommissioning. Section 161.o grants the Commission the power to require licensees to maintain certain necessary documents and to make these available for inspection by the Commission. In addition, the Commission may revoke licenses pursuant to Section 186 of the AEA if it is determined that, had the Commission been aware of the information it now has, it would not have issued the license in the first instance. Section 234 of the AEA also empowers the Commission to impose civil monetary penalties for violations of licensing requirements. Section 232 of the AEA authorizes the Attorney General of the United States to seek, on the Commission's behalf, to enjoin violations of the AEA or regulations and orders issued under it; and Section 223 authorizes the Attorney General to seek fines or imprisonment for violations of certain sections of the AEA, or certain regulations and orders issued under it. Section 235 provides that criminal penalties may be imposed on persons who interfere with inspectors. Section 236 provides that criminal penalties may be imposed on persons who attempt to or cause sabotage at a nuclear facility or to nuclear fuel. Alleged or suspected criminal violations of the AEA are referred to the Department of Justice for appropriate action.

Notwithstanding the \$100,000 limit stated in the AEA, the Commission may impose higher civil penalties as provided by the Debt Collection Improvement Act of 1996. Under this act, the Commission is required to modify civil monetary penalties to reflect inflation. The adjusted maximum civil penalty amount is reflected in Title 10 of the Code of Federal Regulations (10 CFR) 2.205, "Civil Penalties," and the NRC Enforcement Policy.

Question No: 162 Module 08: Enforcement

Ouestion

What methods of enforcement (e.g. warning letters, fines) are available to the Regulatory Body?

Response

The NRC Enforcement Policy supports the NRC's mission to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. Consistent with that purpose, the policy endeavors to deter noncompliance by emphasizing the importance of compliance with NRC requirements, and to encourage prompt identification and prompt, comprehensive correction of violations of NRC requirements to prevent recurrence. Therefore, licensees, contractors, and their employees who do not achieve the high standard of compliance that the NRC expects will be subject to enforcement sanctions. Each enforcement action is dependent on the circumstances of the case. However, in no case will licensees who cannot achieve and maintain adequate levels of safety be permitted to continue to conduct licensed activities.

The NRC's enforcement jurisdiction is derived from the AEA, and the Energy Reorganization Act of 1974, as amended (ERA). Provisions of these Acts authorize the NRC to conduct inspections and investigations and to issue orders. The Acts also authorize the NRC to revoke licenses under certain circumstances, including violations of NRC requirements. The AEA authorized civil penalties at a maximum of \$100,000 per day. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, provides a provision to adjust the civil penalty sanctions to reflect inflation. As a result, the current maximum civil penalty is now \$140,000 per day. Further, the AEA provides for varying levels of criminal penalties (monetary fines and imprisonment) for willful violations of the AEA and regulations or orders issued pursuant to the AEA. Alleged or suspected criminal violations of the AEA are referred to the Department of Justice for appropriate action.

In 10 CFR 2.205, the NRC provides further detail regarding the NRC's use of civil penalties for enforcement.

This Section states that before instituting any proceeding to impose a civil penalty under Section 234 of the AEA, the Executive Director for Operations or the Executive Director's designee, as appropriate, shall serve a written notice of violation (NOV) upon the person charged. The NOV shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged, and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The NOV shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The NOV shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the Commission, if any, unless compromised, remitted, or mitigated, be collected by civil action. The Notice will state that within 20 days of the date of an NOV or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the NOV. The answer to the NOV shall state any facts, explanations, and arguments, denying the charges of violation, or demonstrating any extenuating circumstances, error in the NOV, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty. If the person charged with violation fails to answer within the time specified, an order may be issued imposing the civil penalty in the amount set forth in the NOV. If the person charged with violation files an answer to the NOV, the Executive Director for Operations, or the Executive Director's designee, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civ

The NRC uses a variety of enforcement tools to ensure compliance by licensees, commensurate with the significance of the noncompliance. Guidance regarding disposition of noncompliance issues is described in the NRC Enforcement Manual.

The NRC recognizes several forms of noncompliance, including deviations, nonconformances, and violations. Deviations and nonconformances generally involve failures by the licensee or a contractor to meet commitments it has made to the NRC that are not otherwise legally binding requirements. Actions to correct these types of noncompliance may be provided to the licensee or contractor through either a written Notice of Deviation or Notice of Nonconformance, which are considered administrative actions. Violations, however, are failures by the licensee to meet legally binding regulatory requirements. Regulatory requirements have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance or significance of each violation is assessed as the first step in the enforcement process to determine the appropriate action.

In assessing the significance of a noncompliance, the NRC considers four specific issues: (1) actual safety consequences, (2) potential safety consequences, including the consideration of risk information, (3) potential for impacting the NRC's ability to perform its regulatory function, and (4) any willful aspects of the violation. For certain violations at commercial nuclear power plants, the NRC relies on information from the Reactor Oversight Process's (ROP's) significance determination process (SDP) to evaluate the actual and potential safety significance to provide a risk-informed framework for discussing and communicating the significance of the violation.

Depending on the significance of these findings, the SDP results in assigned colors of green, white, yellow, or red, with red being the most significant. The ROP uses an Action Matrix to determine the appropriate agency response, commensurate with an assessment of overall licensee performance that includes all inspection findings and performance indicators (PIs) over a given interval. If violations that are more than minor are associated with these inspection findings, they will be documented and may or may not be cited in a written Notice of Violation (NOV) depending on the significance. These violations are not normally assigned severity levels, nor are they normally subject to civil penalties. Violations associated with inspection findings that are evaluated by the SDP as white, yellow, or red are considered escalated enforcement and are normally described in a written NOV. Violations associated with green inspection findings are considered nonescalated enforcement and, depending on whether the licensee has taken action to correct the violation, are usually described in an inspection report as a non-cited violation (NCV). Under some conditions though, these violations may result in a written NOV.

Violations that cannot be evaluated through the SDP (i.e., violations that may impact the NRC's ability for oversight of licensed activities and violations that involve willfulness, including discrimination) are evaluated in accordance with the guidance in the Enforcement Policy and assigned an appropriate

severity level. For the purposes of determining the appropriate enforcement action, such violations are normally categorized in terms of four levels of severity to show their relative importance or significance.

Severity Level I has been assigned to violations that are most significant and Severity Level IV violations are the least significant. Severity Level I and II violations are of significant regulatory concern and generally involve actual or high-potential consequences on public health and safety for which a written NOV and Proposed Imposition of a Civil Penalty is normally assigned. Severity Level III violations are cause for significant regulatory concern, for which proposed imposition of a civil penalty is considered based on other factors, including whether there has been other escalated enforcement within the previous 2 years, whether the violation involves willfulness, whether the violation was identified by the licensee, and whether the licensee's corrective actions have been timely and effective. Written orders modifying the license, including suspension of operations, may also be considered for regulatory or safety significant violations.

The NRC normally imposes civil penalties to the licensee organization, but under certain circumstances may impose civil penalties to either individuals or licensee contractor organizations. These actions are rare, since the NRC holds the licensee responsible for the actions of its employees and contractors. For example, in most situations involving Severity Level III or IV violations, no action is taken against an individual, even for willful violations. In addition, the NRC may consider issuing an order banning an individual from licensed activities (usually for a period of from 1 to 3 years) for actions causing a particularly significant violation. Several factors are evaluated in such decisions, such as the level of responsibility of the individual within the licensee organization.

Severity Level IV violations are less serious but are of more than minor concern, and involve noncompliance with NRC requirements that are not considered significant based on risk. Such violations may or may not result in a written NOV depending upon timely corrective actions by the licensee. Normally, these violations are described in an inspection report as an NCV.

The NRC recognizes that there are other violations of minor safety or environmental concern that are below the level of significance of Severity Level IV violations or violations associated with green inspection findings. While licensees must correct these minor violations, they don't normally warrant documentation in inspection reports or inspection records and do not warrant enforcement action. To the extent such violations are described, they will be noted as violations of minor significance that are not subject to enforcement action.

In addition to the normal enforcement tools (NOVs, civil penalties, and orders), under certain conditions, such as a continuing violation of requirements, the NRC may issue a written Confirmatory Action Letter, an administrative action, to document the licensee's commitments to complete corrective actions to restore compliance by a specified date.

Question No: 163 Module 08: Enforcement

Ouestion

How are enforcement actions graded to make them commensurate with the seriousness of the non-compliance? Describe the basic criteria for each type of enforcement action.

Response

(See the response to Question 162.)

In assessing the significance of a noncompliance, the NRC considers four specific issues:

- (1) actual safety consequences
- (2) potential safety consequences, including the consideration of risk information
- (3) potential for impacting the NRC's ability to perform its regulatory function
- (4) any willful aspects of the violation

For most violations at commercial nuclear power plants, the NRC relies on information from the ROP's SDP to evaluate the actual and potential safety significance to provide a risk-informed framework for discussing and communicating the significance of the violation.

NRC inspectors use Inspection Manual Chapter (IMC) 0612, "Power Reactor Inspection Reports," dated April 30, 2010, to perform an initial screening of the inspection results and IMC 0609, "Significance Determination Process," dated August 5, 2008, to assess the significance of inspection findings and any associated violations. When identified during this screening process, violations of a minor nature will be verbally discussed with the licensee to ensure that actions are taken to correct the violation. In addition, minor violations are not normally documented in inspection reports, or to the extent that they must be documented in an inspection report, are described as violations of minor significance that are not subject to enforcement action. However, minor violations can be considered more significant if the licensee willfully fails to take timely corrective actions. Under such conditions, a minor violation's significance can be escalated to at least more than minor (Severity Level IV) and a written NOV can be issued. Other violations that are greater than minor are evaluated using either traditional enforcement or the SDP to assess the significance and determine the appropriate enforcement action.

Violations that cannot be evaluated through the SDP (i.e., violations that may impact the NRC's ability for oversight of licensed activities and violations that involve willfulness, including discrimination) are evaluated in accordance with the Enforcement Policy and assigned an appropriate severity level. For the purposes of determining the appropriate enforcement action, such violations are normally categorized in terms of four levels of severity to show their relative importance or significance.

Severity Level I has been assigned to violations that are most significant and Severity Level IV violations are the least significant. Severity Level I, II, and III violations are considered escalated enforcement. Severity Level I and II violations are of significant regulatory concern and generally involve actual or high-potential consequences on public health and safety for which a written NOV and proposed imposition of a Civil Penalty is normally assigned. Severity Level III violations are cause for significant regulatory concern for which proposed imposition of a civil penalty is considered based on other factors, including whether there has been other escalated enforcement within the previous 2 years, whether the violation involves willfulness, whether the violation was identified by the licensee or the regulator, and whether the licensee's corrective actions have been timely and effective. Written orders modifying the license, including suspension of operations, may also be considered for regulatory or safety significant violations.

All potential Severity Level I, II, and III violations are evaluated at an Enforcement Panel to determine the severity level and the appropriate enforcement action, such as issuance of a written NOV, imposition of a civil penalty, or issuance of an order. The Enforcement Panel includes participants representing several different offices in the NRC that relies upon a collegial process to determine the severity level and associated enforcement sanction for significant violations. The Office of Enforcement participates in every Enforcement Panel to ensure that the enforcement decisions are consistent across the different NRC offices that issue such actions. Normally, Severity Level IV violations are not reviewed at an Enforcement Panel and are documented as NCVs in an inspection report. However, Severity Level IV violations that the licensee failed to restore compliance with in a timely manner, or that the licensee failed to place in its corrective action program to address recurrence, or that was repetitive as a result of inadequate corrective action and was identified by the NRC, or that was willful may result in a written NOV.

Most inspection findings and associated violations at commercial nuclear reactors use the SDP to determine the significance. Depending on the significance of these findings, the SDP results in assigned colors of red, yellow, white, or green. Red has been assigned to findings and associated violations that are most significant and green has been assigned to findings and associated violations of low significance. Similar to use of an Enforcement Panel in traditional cases, those SDP cases that are potentially greater than green are reviewed at a Significance and Enforcement Review Panel (SERP) to determine the significance of the finding and develop the appropriate enforcement action.

All greater than minor findings and associated violations that are evaluated by the SDP will be documented in an inspection report and may or may not be cited in a written NOV depending on the significance. Violations associated with inspection findings that are evaluated by the SDP as white, yellow, or red are considered escalated enforcement and are normally described in a written NOV. Violations associated with green inspection findings are considered nonescalated enforcement and, depending on whether the licensee has taken action to correct the violation, are usually described in an inspection report as an NCV. Green violations also may be cited in a written NOV under similar conditions to that of Severity Level IV violations, except for cases involving repetitiveness.

Typically, if a violation is cited in a written NOV, then the licensee is required to provide a written response describing the actions taken to restore compliance and to prevent recurrence. Normally, SDP evaluated violations are not subject to civil penalties; although, the NRC reserves the use of discretion for particularly significant violations to assess civil penalties in accordance with Section 234 of the AEA. In addition to issuance of a written

NOV, the NRC's ROP uses an Action Matrix to determine additional agency actions, commensurate with an assessment of overall licensee performance, including performance trend information. These actions may include, depending upon the assessment of inspection findings and PIs, discussion of the issues at one or more regulatory conferences and the scheduling of additional supplemental inspections to determine if the licensee's corrective actions are effective. Again, depending upon the assessment, the supplemental inspection effort can range from about an additional 40 hours (IP 95001, "Inspection for One or Two White Inputs in a Strategic Performance Area," dated November 9, 2009) for a single white finding, to upwards of 2,000 hours (IP 95003, "Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs or One Red Input," dated November 9, 2009) for significant performance deficiencies, such as multiple yellow and white findings or a red finding.

Question No: 164	Module 08: Enforcement
Question	

What enforcement actions does the Regulatory Body take:

I.For deviations or violations having minor safety significance;

II.For more serious violations (e.g. imminent radiological hazard);

Response

(See the response to Question 162 for complete information regarding the NRC enforcement process.)

I. Regarding deviations that have minor safety significance, the NRC recognizes several levels of significance when using either the traditional enforcement process (normally reserved for violations involving willful aspects or having an impact on the ability of the NRC to regulate) or the ROP SDP. In the traditional enforcement process, NRC uses four severity levels, with Severity Level I being most significant and Severity Level IV being least significant. In the ROP, NRC uses four color-coded levels to denote significance, with red being most significant and green being least significant.

Violations or noncompliances that have the least significance (either Severity Level IV or green) are written in inspection reports and provided to the licensee for corrective action. Most of these violations are not cited in a written NOV, but rather are treated as NCVs, in which case, the licensee is not required to provide a formal written response. In order for the NRC to treat these lower significance violations as noncited, the licensee must have entered the issue into its corrective action program for ultimate resolution including development of corrective and preventive actions. The NRC expects that the licensee will correct these NCVs within a reasonable time, however no further direction is provided to the licensee. Normally, resolution of these issues is evaluated by the NRC on a sampling basis during conduct of the baseline inspection of the licensee's corrective action program effectiveness.

Under certain circumstances, the NRC will issue a written NOV for these lower significant violations. The written NOV provides directions to the licensee to provide a formal written response within 30 days including the following information: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Normally, resolution of these issues is evaluated by the NRC on a sampling basis during conduct of the baseline inspection of the licensee's corrective action program effectiveness (10 CFR 2.201, "Notice of Violation," provides details related to issuance and response to NOVs).

The NRC recognizes that there are other violations of minor safety or environmental concern below the level of significance of Severity Level IV violations or violations associated with green inspection findings. While licensees must correct these minor violations, they do not normally warrant documentation in inspection reports or inspection records and do not warrant enforcement action. To the extent that minor violations are described in a written inspection report, they will be noted as violations of minor significance that are not subject to enforcement action. Normally, NRC inspectors verbally discuss minor violations with the licensee when they are identified to ensure that the licensee takes appropriate action.

II. More serious violations (Severity Level III or NOVs associated with white findings) are provided to the licensee in a written NOV. Before the NRC issues a final written notice for such serious violations, the licensee is invited to attend either an enforcement conference (for traditional violations) or a regulatory conference (for violations using the ROP) to discuss the circumstances surrounding the violation, to provide its evaluation of the significance, and to provide a description of the corrective actions taken or planned and the results achieved. Optionally, the licensee may decline attending the conference and may provide a written response describing the same information that would be discussed at the conference. Subsequent to receipt of the licensee's information, the NRC will evaluate this information and determine the final significance or severity level and appropriate enforcement action. The final determination will be reflected in the written notice.

Serious violations also may be considered for issuance of a civil penalty, although civil penalties are not normally issued for violations evaluated through the ROP and assigned a color. Depending on the nature of the violation, the NRC may also issue an order requiring specific licensee actions. The licensee is required to respond to the written notice and must follow the directions provided. According to the type of notice, whether it involves a proposed imposition of a civil penalty or not, the licensee is provided specific direction regarding the actions it must take, including as appropriate, (1) how to pay the civil penalty, (2) responding by providing information about the licensee's actions to correct the violation and prevent its recurrence (as described in Section I above), or (3) providing a response denying the violation or appealing the civil penalty, in whole or in part, or both. (In 10 CFR 2.205, the NRC provides details regarding the disposition of civil penalties.)

For serious violations limited to violations involving willful acts, the NRC also offers the licensee or individual the opportunity to use Alternate Dispute Resolution (ADR) in lieu of the traditional enforcement process. If both parties agree to use ADR, then a mediation session will be held to resolve the issue. If both parties agree to a resolution at the mediation session, then the NRC will issue its final enforcement action in a Confirmatory Order to the licensee or individual. The Confirmatory Order provides a written directive confirming the terms of the resolution agreed upon at the mediation session. If the parties cannot agree to a resolution through ADR, then the NRC will use the traditional enforcement tools described above to disposition the violation.

For violations associated with ROP safety significant findings of white, yellow, or red, additional inspection activities would be implemented based on the overall performance of the licensee to ensure that the licensee's corrective actions were appropriate, and additional oversight would occur including regulatory performance meetings, as appropriate. These actions would be taken as described in the NRC Action Matrix. For the violations associated with the most safety-significant inspection findings, characterized as red, the NRC considers transitioning the facility from the normal ROP to the IMC 0350 ("Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns," dated December 15, 2006) oversight process. Normally, a facility in this process would be in a shutdown condition, and either by order or by means of a Confirmatory Action Letter (CAL), the facility would remain shut down until the NRC determined that the necessary corrective actions and improvements to the licensee's organization were completed.

III. In the event of extremely serious noncompliance or release of radioactive material, the NRC may take several actions. Initially, the NRC may consider issuing either a CAL or an Immediately Effective Order to require the licensee to complete those actions necessary to restore compliance. A CAL is an administrative action that confirms in writing the licensee's commitment to take specified corrective actions to restore compliance within an agreed upon time. CALs are normally issued by one of the regional offices or the Office of Nuclear Reactor Regulation (NRR).

An Immediately Effective Order would provide a similar outcome, but an order must be followed by the licensee or additional enforcement sanctions could be applied. An order is a written directive to modify, suspend, or revoke a license, to cease and desist from a given practice or activity, or to take such other action as may be proper, such as by requiring the facility to shut down or remain shut down until the noncompliance is corrected. In such unusual circumstances, requirements beyond the current existing regulatory framework may have to be imposed to provide reasonable assurance of public health and safety. In such circumstances, the NRR may issue Safety Orders to impose the additional requirements. When significant violations of NRC requirements are involved, in accordance with its Enforcement Policy, the NRC may issue an order based on the noncompliance. These orders (Enforcement Orders) may order compliance or additional actions in light of the noncompliance, such as requiring third-party audits. Typically, the NRC regions or the program office responsible for the inspection area or activity would initiate Compliance Orders. (In 10 CFR 2.202, "Orders," the NRC provides details regarding the use of orders.)

Enforcement Orders can be issued by the Director, Office of Enforcement or the Deputy Executive Director for Operations. The authority to issue orders related to specific violations is contained in a delegation of authority memorandum issued from the Deputy EDO to the Office of Enforcement. Most extremely serious noncompliance situations, especially those involving actual safety consequences, would be evaluated under traditional enforcement, assigned a severity level, and likely would involve issuance of a civil penalty, an order, or both. Also, the NRC has the authority to revoke a license for violations of this nature. Again, as described previously, the NRC would consider transitioning the facility from the normal ROP to the IMC 0350 oversight process for these situations.

Question No: 165 Module 08: Enforcement

Ouestion

Do written warnings or directives identify the nature and basis for the violation and a period for taking corrective action? If not, why not?

Response

The NRC uses a variety of enforcement tools to ensure compliance by licensees, commensurate with the significance of the noncompliance. Guidance regarding disposition of noncompliance issues is described in the NRC Enforcement Manual. (See the response to Question 162 for a detailed description of the enforcement process.)

The NRC Enforcement Policy and Enforcement Manual describe two types of enforcement action, escalated and nonescalated. Escalated enforcement is used for significant or serious violations of requirements, including such actions as civil penalties and written orders modifying or revoking the license. Alleged or suspected criminal violations of the AEA are referred to the Department of Justice for appropriate action. Escalated enforcement involves Severity Level I, II, or III violations for traditional enforcement actions, and violations associated with red, yellow, or white inspection findings for enforcement under the ROP.

Nonescalated enforcement is used for Severity Level IV violations or violations associated with green inspection findings. Severity Level IV violations and violations associated with green inspection findings are of low significance but are of more than minor concern. Depending on whether or not the licensee has taken action to correct the violation, these issues are usually described in an inspection report as NCVs. Under some conditions though, these violations may result in a written NOV.

For these issues involving minor safety significance, the NRC describes the nature and basis for the violation in a written inspection report. As a minimum for NCVs, the report will provide a description or characterization of the violation, an analysis of its significance or severity and the basis for such, as well as a description of the requirements that were not met and how the licensee failed to meet them. Also, if, for example, the violation was not being corrected by the licensee, the NRC could also issue a written NOV, usually enclosed with the inspection report, which would require a formal written response by the licensee addressing: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. While licensees are not required to respond to NCVs, 10 CFR 2.201 requires the licensee to respond to a NOV within 20 days of the date of the violation (or other specified time as directed by the written notice).

In 10 CFR 2.201, the NRC provides the details related to issuance and response to NOVs, as follows: in response to an alleged violation or the conditions of a license or an order issued by the Commission, the Commission may serve on the licensee or other person subject to the jurisdiction of the Commission a written notice of violation; a separate notice may be omitted if an order or demand for information is issued that otherwise identifies the apparent violation; and the notice of violation will concisely state the alleged violation and may require that the licensee or other person submit, within 20 days of the date of the notice or other specified time, a written explanation or statement in reply if the Commission believes that the licensee has not already addressed all the issues contained in the notice of violation.

The NRC assesses the licensee's development and completion of corrective actions, including the timeliness of those actions, during routine baseline inspection of the licensee's corrective action program. The NRC allows the licensee to determine the timing of the completion of these actions, but assesses the effectiveness of the actions, including whether or not the violation is repeated. As such, the NRC describes the corrective actions, if known, in the inspection report, or directs the licensee to respond to a NOV within 20 days to provide such information. As a result, the NRC does not provide, either in the written inspection report or a written NOV, a directive about when completion of the corrective actions is required.

Question No: 168 Module 08: Enforcement

Question

Question

Are all enforcement decisions confirmed to the operator in writing?

Response

The NRC enforcement process ensures that all enforcement decisions are confirmed to the licensee in writing, with the exception of minor violations. Minor violations are below the significance of green inspection findings or Severity Level IV violations and have insignificant safety or regulatory impact. As a result, minor violations are not normally documented. The inspector discusses minor violations with the licensee's representatives to ensure that the violations will be corrected. All other enforcement actions and decisions are provided to the licensee in writing. The level of detail in writing is dependent upon the nature and significance of the violation and enforcement decision.

NRC reactor program inspectors do not have the authority to issue on-the-spot enforcement; however, they are permitted to discuss their observations with licensee representatives. (Note: in some cases, materials program inspectors have been granted limited on-the-spot enforcement authority to issue Severity Level IV violations using NRC Form 591, "Safety and Compliance Inspection.") For more serious violations involving the health and safety of workers or the public, or environmental or safeguards concern, inspectors immediately discuss the issue with senior licensee representatives to ensure that the licensee is evaluating the concern for appropriate action. The inspectors also immediately inform NRC management of the concern, so that the NRC can consider possible actions, including issuing a CAL or order, as needed to restore compliance and ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. This action would precede other enforcement actions to address the noncompliance and correct its related root causes.

The NRC uses a variety of enforcement tools to ensure compliance by licensees, commensurate with the significance of the noncompliance. Guidance regarding disposition of noncompliance issues is described in the NRC Enforcement Manual.

During significant steps of the enforcement process the licensee is informed in writing of the NRC actions.

The NRC enforcement process includes several key steps from discovery of the concern until issuance of the final enforcement action. Initially, the concern is discovered generally during an NRC inspection or investigation. In most cases, the concern is verbally described to the licensee at an inspection exit meeting, absent any characterization of the significance or severity level of the violation. Next, the inspectors assess the preliminary significance using screening tools developed for the ROP, or in accordance with the Enforcement Policy, as appropriate for traditional enforcement issues. If the concern is minor, then no additional documentation of the violation is required. If the concern is determined to be greater than minor and either green or Severity Level IV (for traditional enforcement issues), then the NRC office responsible for conducting the inspection will issue a written inspection report describing the violation and its significance and will generally describe the issue as an NCV. In some unusual cases, as described in the Enforcement Policy and Enforcement Manual, an NOV may be issued to the licensee with the inspection report in lieu of an NCV. Generally, issuance of the inspection report completes the NRC enforcement action for these low significance issues.

For more serious issues, such as Severity Level I, II, or III violations, or violations associated with inspection findings that are red, yellow, or white, the NRC holds an enforcement panel or SERP to determine the severity or significance of the violation prior to issuing the inspection report to the licensee. The office conducting the inspection will prepare a panel worksheet describing the concern, providing its assessment of the significance, and recommending an enforcement decision for NRC consideration. The panel will discuss the information provided and make a decision regarding enforcement.

(An enforcement panel is used for traditional enforcement actions resulting from violations, for example, that may have willful aspects or have an impact on the NRC's ability to regulate licensed activities. A SERP is used for enforcement related to the ROP. The SERP generally uses a risk-informed approach to assess the significance of the inspection finding and to characterize any associated violations. Both processes work similarly.)

Generally, significant violations will result in issuing either a written choice or a conference letter to the licensee. A choice letter describes the apparent violations that are being considered for escalated enforcement action and provides the licensee an option to either attend a meeting to discuss the apparent violations and describe its corrective actions, or to otherwise address the apparent violations in a written response. A conference letter also describes the apparent violations that are being considered for escalated enforcement and requests the licensee to attend a meeting to address the apparent violations. Usually, the choice or conference letter also forwards the written inspection report and any other information necessary to support the NRC's preliminary significance or severity level determination. The choice or conference letters usually request the licensee to respond in writing or attend the conference within about 30 days of the date of the letter issuance. This is to ensure that corrective actions are developed in a timely manner.

After the licensee addresses the apparent violations, either in writing or at the conference, the NRC holds a second panel or postconference caucus to discuss the information that the licensee has provided. (In the case of traditional enforcement violations, the NRC considers corrective actions to be timely if they are described to the NRC prior to issuance of the final enforcement action, for example at the enforcement panel, and are completed in a reasonable time given the nature and circumstances of the causes that led to the violation.) At the postconference caucus, the NRC will determine the final significance or severity level of the apparent violations and decide an appropriate enforcement action. The final enforcement action will be issued to the licensee in writing and will include, as appropriate, an NOV, an NOV and Proposed Imposition of Civil Penalty, an order, or an NOV and order. However, unless a separate response is warranted, an NOV need not be issued where an order is based on violations described in the order. The NOV (or order) will describe the nature and significance of the violation, as well as the regulatory basis for the violation. Also, the NOV (or order) will include written instructions to the licensee regarding its response and the time in which it must respond.

Question No: 169 Module 08: Enforcement

Ouestion

At what level in the Regulatory Body can enforcement decisions be made? Who within the Regulatory Body has the authority to extend allowed times for corrective actions?

Response

NRC reactor inspectors do not have the authority to issue on-the-spot enforcement; however, they are expected to discuss their observations with licensee representatives, including discussions regarding preliminary performance deficiencies or violations of requirements. Final enforcement actions are issued by various levels of NRC management, according to the significance of the violation or the nature of the enforcement action. Most nonescalated enforcement, involving ROP findings of green significance or Severity Level IV violations, are issued by the branch chief of the office involved in the inspection activity, normally the inspector's first-level supervisor. Most escalated enforcement actions, such as involving greater-than-green findings or Severity Level I, II, or III violations with or without civil penalties, are issued by the regional administrator of the affected regional office responsible for the inspection activity. Other escalated enforcement action, including issuing orders to modify or suspend licensed activities, are issued by the Deputy Executive Director for Operations or the Director, Office of Enforcement. The recommended enforcement decision for all escalated enforcement actions is made by an enforcement panel consisting of representatives from different parts of the NRC organization, including the affected regional office, the knowledgeable program offices for the site and topic, the Office of Enforcement, and the Office of General Council, if the enforcement action could result in a hearing.

For urgent serious violations involving the health and safety of workers or the public, or environmental or safeguards concern, NRC reactor inspectors immediately discuss the issue with senior licensee representatives to ensure that the licensee is evaluating the concern for appropriate action. The inspectors also immediately inform NRC management of the concern, so that the NRC can consider possible actions, including issuing a CAL or order, as needed, to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. Normally, CALs are issued by the responsible office director or regional administrator. Subsequent to the immediate action to restore compliance and to ensure adequate protection, the NRC will determine if and to what degree enforcement will be taken for the issue. In most cases, at least an NOV will be issued.

Regarding corrective actions, the authority to extend the due date for a corrective action is dependent upon the type of enforcement action that had been taken. For nonescalated enforcement actions, generally the branch chief of the affected office responsible for the inspection activity can authorize an extension for corrective action completion or other appropriate revisions to the licensee's corrective actions. For escalated enforcement actions, generally the NRC official who signed out the original enforcement action has the authority to extend the time for completing the corrective actions; however, this would be coordinated with the Office of Enforcement and likely would be discussed at an enforcement panel to decide upon a recommended course of action. Finally, for escalated enforcement involving orders, the order provides specific direction regarding who in the NRC has the authority to relax provisions of the order, including the timeliness of actions. Typically, the regional administrator of the affected regional office is granted this authority.

Question No: 170 Module 08: Enforcement

Ouestion

Is the regulatory inspector empowered to take on the spot enforcement actions? If so, how and to what extent?

Response

NRC reactor inspectors do not have the authority to issue on-the-spot enforcement; however, they are expected to discuss their observations with licensee representatives, including discussions regarding preliminary performance deficiencies or violations of requirements. The final enforcement actions are issued by various levels of NRC management, according to the significance of the violation or the nature of the enforcement action.

The NRC has established an enforcement policy that addresses the enforcement actions within the national legal framework for all noncompliances of the rules and regulations and provisions of any authorized licenses issued by the NRC. This Enforcement Policy and associated guidance information described in the Enforcement Manual provide a description of the NRC's enforcement process, as well as a description of the possible enforcement actions for all noncompliances. (See the responses to Question 162 and 163 for specific information regarding the enforcement actions that the NRC can take.)

As described in the Enforcement Manual, the NRC dispositions noncompliances in a graded manner according to the significance or severity of the issues. Typically, less significant noncompliances are dispositioned as NCVs that are documented in written inspection reports. These reports are reviewed, approved, and issued by the NRC management of the office in charge of the inspection activity that identified the noncompliance, usually by an NRC regional office branch chief. More significant noncompliances, involving escalated enforcement actions, require a review by a panel of representatives from several NRC offices, coordinated by the Office of Enforcement, to determine the final significance or severity of the violation and the appropriate enforcement action, such as an NOV, a civil penalty, or an order. The final enforcement action for significant violations is typically issued by the regional administrator of the regional office who has oversight for the facility.

For urgent serious violations involving the health and safety of workers or the public, or environmental or safeguards concern, the NRC reactor inspectors immediately discuss the issue with senior licensee representatives to ensure that the licensee is evaluating the concern for appropriate action. The inspectors also immediately inform NRC management of the concern, so that the NRC can consider other possible actions, including issuing a CAL or order, as needed, to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment prior to issuing the final enforcement action. Normally, CALs are issued by the responsible office director or regional administrator. Orders, related to specific violations of NRC requirements, are issued by the Director, Office of Enforcement or the Deputy Executive Director for Operations.

Question No: 170AS Module 08: Enforcement

Ouestion

How does the Regulatory Body ensure enforcement activities do not lead to a reluctance on the part of the operator to voluntarily come forward with safety related issues?

Response

The NRC has established an enforcement policy that addresses the enforcement actions within the national legal framework for all noncompliances of the rules and regulations and provisions of any authorized licenses issued by the NRC. The Enforcement Policy and associated guidance information described in the Enforcement Manual provide a description of the NRC's enforcement process, as well as a description of the possible enforcement actions for all noncompliances. (See the responses to Questions 162 and 163 for specific information regarding the enforcement actions that the NRC can take.)

As described in the Enforcement Policy and Enforcement Manual, the NRC dispositions noncompliances in a graded manner according to the significance or severity of the issues. Typically, less significant noncompliances are dispositioned as NCVs that are documented in written inspection reports. Further, the NRC treats such low significance issues, if initially identified and corrected by the licensee and reported to the NRC if so required, as Licensee Identified Violations. Licensee Identified Violations are described in NRC inspection reports and treated as NCVs and appropriate credit is described for the licensee's identification of the issue. Also, such issues are not considered in the NRC assessment process per IMC 0305 ("Operating Reactor Assessment Program," dated December 24, 2009) as are other inspection findings. Therefore, the NRC fosters the licensee's efforts to self-identify, correct, and voluntarily come forward with such low-significance violations by not considering these issues during the assessment process.

However, the NRC Enforcement Policy recognizes that more significant violations warrant enforcement action even if identified by the licensee. In such cases, for example involving a performance deficiency and violation with a significance determination of greater-than-green, the licensee will likely receive an NOV. Further, the issue will be considered when the NRC conducts its assessment activities under the ROP. However, since the licensee identified this issue and likely reported the condition and corrective actions to the NRC prior to the enforcement action, the NOV may be issued without requiring a response by the licensee.

Similarly, when the NRC is using its traditional enforcement process for significant violations involving actual or potential safety consequences, willfulness, or that impact the regulatory process, credit for identification may be considered during the civil penalty assessment process when determining the appropriate enforcement action. For example, if the licensee has had prior escalated enforcement within 2 years of a current licensee-identified Severity Level III violation, then the civil penalty assessment process would normally result in either no civil penalty or a base civil penalty, based on whether the licensee's corrective action is judged to be reasonably prompt and comprehensive. On the contrary, when the licensee is not given credit for identification under the same conditions, the civil penalty assessment process would normally result in either a base civil penalty or a base civil penalty escalated by 100 percent, depending upon the quality of the licensee's corrective action, because the licensee's performance is clearly not acceptable. For these more significant violations involving escalated enforcement, a description of the licensee's identification of the matter and the credit granted, if any, is provided in the letter forwarding final enforcement action.

When the NRC is determining the appropriate enforcement sanction for a significant violation, whether the issue is treated under the ROP or through traditional means, the NRC typically offers the licensee an opportunity to discuss the violation, including its view on the significance, its corrective actions, and any other important characteristics of the violation such as discovery and extent of condition information. The licensee can either provide this information at a meeting, such as at a regulatory conference or a predecisional enforcement conference, or may provide the information in a written response. The NRC enforcement process provides this opportunity in order to foster mutual understanding and respect between itself and its licensees through a frank, open, and yet formal relationship, such that there is constructive two-way interaction on significant safety-related issues.

Therefore, although the NRC treats enforcement issues with a graded approach based on the violation significance or severity level, the Enforcement Policy and the ROP both recognize and give appropriate credit to the licensee for its identification of safety issues and seeks input from the licensees on significant enforcement matters such that enforcement should not lead to a reluctance on the part of the licensee to voluntarily come forward with safety issues.

Question No: 172 Module 08: Enforcement

Ouestion

Does the operator have the right to appeal against enforcement decisions? If so, what are they and how are differences of view resolved?

Response

The authority for the licensee to challenge enforcement actions is contained in NRC regulations, primarily in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders." Licensees can challenge enforcement actions for several reasons; for example, a licensee might dispute the requirements, the facts of the case, the agency's application of the Enforcement Policy, or the significance of the violation. Licensees may provide clarifying information that was not available at the time of the inspection, which may affect the finding of noncompliance.

In addition, the notice (typically the NOV) that forwards cited violations provides specific actions for the licensee to take to dispute or challenge the associated enforcement action. For significant cases involving an enforcement order, the licensee is granted rights described in the order to request a hearing to stay or rescind the action within a specified time. For other significant actions involving civil penalties, the licensee can dispute the violation or appeal the application of the civil penalty in whole or in part. For ROP enforcement actions, the licensee can dispute the violation as well as appeal the results of the SDP. Information regarding such appeals is contained in Attachment 2, "Process for Appealing NRC Characterization of Inspection Findings (SDP Appeal Process," To IMC 0609, dated January 31, 2008. Lastly, for violations that are treated as NCVs, typically the letter from the NRC to the licensee forwarding the NCV will describe that the licensee can dispute or challenge such NCVs.

During calendar year (CY) 2008, the agency did not withdraw any escalated enforcement.

In addition, the NRC Office of Enforcement has established a metric for quality of enforcement actions based on the number of disputed and withdrawn nonescalated enforcement actions. The goal is less than 30 withdrawn nonescalated enforcement actions in a calendar year. This metric does not include violations that are withdrawn on the basis of supplemental information that was not available to the NRC inspector prior to issuance of the enforcement action. During CY 2008, the agency issued approximately 1,160 nonescalated enforcement actions to reactor, materials, and fuel facility licensees. Of these actions, only 12 nonescalated enforcement actions were disputed. The NRC subsequently withdrew the violations entirely or in part in only three of the 12 disputed cases.

Question No: 178 Module 08: Enforcement

Question

How is the enforcement policy and enforcement process communicated to the staff and to operators?

Response

The NRC Office of Enforcement maintains a Web site through the NRC Web site on which enforcement information is provided to all interested parties including internal NRC staff, licensees, and members of the public. The NRC Enforcement Policy, Enforcement Manual, and a description of significant enforcement actions are examples of the information that are available on the Enforcement Web site. In addition, the NRC publishes changes to the Enforcement Policy in the Federal Register.

The NRC Enforcement Manual is the primary source of guidance regarding agency policy and procedures for NRC staff implementing the enforcement program. The manual contains procedures, requirements, and background information that are essential to those who develop or review enforcement actions for the NRC. The manual provides guidance consistent with the NRC Enforcement Policy. Since most enforcement actions are initiated from the regional offices, the Enforcement Manual is structured to reflect that the regional offices initiate, recommend, or issue enforcement actions. However, all offices that conduct inspections and determine compliance should follow the guidance in the manual. Program offices, such as NRR, the Office of Nuclear Material Safety and Safeguards, the Office of New Reactors, or the Office of Nuclear Security and Incident Response, that take the lead for an enforcement action assume the responsibilities of both the program office and the regional office for that action.

The Enforcement Manual is a living document and is maintained on the NRC Enforcement Web site. Changes to the manual are contained in Change Notices posted in the Change Notice Index on the Enforcement Web site. Enforcement Policy changes are also documented annually in the NRC Enforcement Program Annual Report. In addition, the Enforcement Manual contains temporary guidance in the form of Enforcement Guidance Memoranda. These temporary guidance procedures provide greater specificity for the staff in handling unique enforcement situations.

In addition to the enforcement-related information that is available to the staff, licensees, and the public through the Office of Enforcement Web site, the NRC periodically issues generic communications to its licensees regarding changes to the enforcement program. These communications, generally in the form of an information notice or a regulatory information summary, provide no new requirements; however, they generally describe recent significant inspection findings or changes in the guidance and practices for all regulatory matters, including enforcement.

Regarding staff training, NRC reactor inspectors must successfully complete a training and qualification program prior to conducting independent inspection activities. This qualification program is described in NRC IMC 1245, "Qualification Program for Operating Reactor Programs," dated November 9, 2009. This program provides basic inspector competencies covering the safety principles, concepts, and technological aspects, as well as the procedures used by the NRC for licensing, inspection, and enforcement. One of the elements of this program, contained in IMC 1245, Appendix A, "Basic-Level Training and Qualification Journal," dated July 8, 2009, includes an independent study activity for the enforcement program and processes, during which the inspector trainee reviews the Enforcement Policy, Enforcement Manual, and appropriate guidance in the Inspection Manual relative to enforcement using either the traditional tools or the ROP. All inspectors complete this activity prior to basic inspector certification. In addition, refresher training is generally provided annually to all inspectors covering a number of topics, including enforcement.

Question No: 179 Module 08: Enforcement

Ouestion

Is there additional training for staff members involved in the enforcement process?

Response

(See the response to Question 178.)

NRC reactor inspectors must successfully complete a training and qualification program prior to conducting independent inspection activities. This qualification program is described in NRC IMC 1245. This program provides basic inspector competencies covering the safety principles, concepts, and technological aspects, as well as the procedures used by the NRC for licensing, inspection, and enforcement. One of the elements of this program, contained in IMC 1245, Appendix A, includes an independent study activity for the enforcement program and processes, during which the inspector trainee reviews the Enforcement Policy, Enforcement Manual, and appropriate guidance in the Inspection Manual relative to enforcement using either the traditional tools or the ROP. All inspectors complete this activity prior to basic inspector certification. Also, IMC 1245 requires inspectors to complete additional training activities, including associated enforcement topics, for each qualification card, for example, IMC 1245, Appendix C1, "Reactor Operations Inspector Technical Proficiency Training and Qualification Journal." These activities, excepting refresher training elements, must be completed before an inspector is qualified to conduct independent inspections. In addition, refresher training is generally provided annually to all inspectors covering a number of topics, including enforcement. Finally, the NRC enforcement staff is generally made up of former qualified inspectors or qualified license reviewers.

The NRC Office of Enforcement provides periodic internal training on enforcement-related topics, generally involving process changes, to staff members involved in the enforcement process. These activities are conducted weekly for Office of Enforcement staff in Headquarters. In addition, counterpart meetings are held at least annually to include enforcement staff from the regional and program offices as well as the Office of Enforcement during which enforcement-related training is provided.

Question No: 180	Module 08: Enforcement
Question	
Is there a graded approach to enforcement?	

Response

(See also the response to Question 163.)

This graphic represents the NRC's graded approach to dealing with violations, both in terms of addressing their significance and developing sanctions.

The NRC assesses the significance of a violation by considering the following:

-actual safety consequences

-potential safety consequences

-potential for impacting the NRC's ability to perform its regulatory function

-any willful aspects of the violation

Violations are assigned a severity level ranging from Severity Level I for the most significant violations to Severity Level IV for those of more than minor concern.

Issues assessed through the ROP SDP are assigned a color (i.e., red, yellow, white, or green) based on the risk significance, red being the most significant and green being the least significant.

Minor violations must be corrected; however, given their limited risk significance, they are not subject to enforcement action and are not normally described in inspection reports.

Generally, violations are identified through inspections and investigations. All violations are subject to civil enforcement action, and some may also be subject to criminal prosecution. When an apparent violation is identified, it is assessed using the guidance in the NRC Enforcement Manual, in accordance with the Enforcement Policy.

There are three primary enforcement sanctions available: NOVs, civil penalties, and orders.

An NOV is a written notice that concisely identifies an NRC requirement and how it was allegedly violated. The NOV may require a written explanation or statement in reply in accordance with the guidance provided in the notice (i.e., 10 CFR 2.201 specifies that the licensee or other person submit a written explanation or statement in reply within 20 days of the date of notice or other time specified in the notice. The staff may allow additional time to respond upon a showing of good cause).

A CP is a monetary fine that is used to emphasize compliance in a manner that deters future violations and to focus a licensee's attention on significant violations. Accordingly, different levels of penalties are provided in Tables 1 and 2, "Base Civil Penalties," of the Enforcement Policy. Civil penalties are issued under the authority of Section 234 of the AEA or Section 206 of the ERA. Section 234 of the AEA provides for penalties up to \$100,000 per violation per day. This amount has been adjusted for inflation by the Debt Collection Improvement Act of 1996 and is currently \$140,000.

Orders can be used to modify, suspend, or revoke licenses or require specific actions by licensees or other persons. Orders can also be used to impose civil penalties. The Commission's order-issuing authority under Section 161 of the AEA is broad and extends to any area of licensed activity that the Commission deems necessary to promote the common defense and security or to protect health or to minimize danger to life or property. In addition, as a result of a 1991 rulemaking, the Commission's regulations now provide that orders may be issued to persons who are not themselves licensed.

After an apparent violation is identified, the next step is to gather information about the apparent violation and, thereafter, to assess its significance. Violations are assigned a severity level that reflects their seriousness and safety significance, which, in turn, determines how the violation should be dispositioned. Severity levels range from Severity Level I, for the most significant violations, to Severity Level IV for those of more than minor concern. Minor violations are below the significance of Severity Level IV violations and are typically not the subject of enforcement action. Nevertheless, the root causes of minor violations must be identified, and appropriate corrective actions must be taken to prevent recurrence. In many cases, licensees who identify and promptly correct nonrecurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as NCVs as provided in Section VI.A of the Enforcement Policy.

When escalated enforcement action appears to be warranted (i.e., Severity Level I, II, or III violations, civil penalties or orders), a predecisional enforcement conference (PEC) may be conducted with a licensee before the NRC makes an enforcement decision. A PEC may also be held when the NRC concludes that it is necessary or the licensee requests it. The purpose of the PEC is to obtain information that will assist the NRC in determining the appropriate enforcement action. The decision to hold a PEC does not mean that the agency has determined that a violation has occurred or that enforcement action will be taken. If the NRC concludes that a conference is not necessary, it may provide a licensee with an opportunity to respond to the apparent violations in writing or by requesting a PEC before making an enforcement decision.

Civil penalties are normally assessed for Severity Level I and II violations and for NRC-identified violations involving knowing and conscious violations of the reporting requirements of Section 206 of the ERA. Civil penalties are considered for Severity Level III violations.

If a civil penalty is to be proposed, a written NOV and proposed imposition of a civil penalty must first be issued. The NOV must advise the person charged with the violation that the civil penalty may be paid in the amount specified, or the proposed imposition of a civil penalty may be contested in whole or in part by a written response, either denying the violation or showing extenuating circumstances. The NRC will evaluate the response and use that information to determine if the civil penalty should be mitigated, remitted, or imposed by order. Thereafter, the licensee may pay the civil penalty or request a hearing.

Orders may be used to modify, suspend, or revoke licenses. Orders may require additional corrective actions, such as removing specified individuals from licensed activities or requiring additional controls or outside audits. Persons adversely affected by orders that modify, suspend, revoke a license, or take other action may request a hearing.

In addition to the orders used to modify, suspend, or revoke licenses, the agency may issue a Demand for Information (DFI). A DFI is a significant enforcement action that can be used with other enforcement actions such as an imposition of a civil penalty. As its name implies, a DFI is a request for information from licensees and applicants for a license, vendors, and contractors, in order to determine, for example, whether a license should be granted, suspended, or revoked, or whether further enforcement action is warranted.

The ROP utilizes the results of PIs and baseline inspection findings to determine the appropriate regulatory action to be taken in response to a licensee's performance. Because there are many aspects of facility operation and maintenance, the NRC inspects utility programs and processes on a risk-informed sampling basis to obtain representative information. The objective is to monitor performance in three broad areas: reactor safety (avoiding accidents and reducing the consequences of accidents if they occur); radiation safety for both plant workers and the public during routine operations; and protection of the plant against sabotage or other security threats. The ROP has been in effect since April 2000.

Under the ROP, the staff assesses certain inspection findings at nuclear power plants through the SDP. The SDP is a risk-informed framework that was developed to evaluate the actual and potential safety significance of these findings. Such findings may contribute to potential safety concerns or programmatic weaknesses that do not violate NRC regulations. The SDP provides a basis for discussing and communicating the significance of such findings with the licensee. Some findings are associated with violations of the regulations. The final disposition of the violations associated with findings that have been evaluated through the SDP is contingent on the risk significance attributed to the findings (assigned the colors of green, white, yellow, or red with increasing risk). The Enforcement Policy has been revised to state that regulatory conferences will be conducted in lieu of PECs if violations are associated with risk-significant findings evaluated through the SDP. The policy notes that regulatory conferences are conducted to discuss the significance of findings evaluated through the SDP with or without associated violations. The focus of these meetings is on the significance of the issues and not necessarily on the correction actions associated with the issue. Because the significance assessment from the SDP determines whether or not escalated enforcement action will be issued, a subsequent PEC is not normally necessary. In addition, the Enforcement Policy has been modified to clarify that the mitigation discretion addressed in Sections VII.B.2–VII.B.6 (e.g., violations identified during shutdowns, involving past enforcement actions, old design issues, or special circumstances) does not normally apply to violations associated with issues evaluated by the SDP.

The NRC will normally take an enforcement action against an individual only if the staff is satisfied that the individual fully understood, or should have understood, his or her responsibility; knew or should have known, the required actions; and knowingly or with careless disregard (i.e., with more than mere negligence) failed to take required actions that have actual or potential safety significance. Actions can be taken directly against individuals either because they are individually licensed or because they violated the rules on deliberate misconduct. Generally, when enforcement action is taken against an individual, enforcement action is taken against a licensee.

A Statute of Limitations is applicable to NRC civil penalty cases (see 28 USC 2462), and requires that the NRC initiate an action imposing a civil penalty, issuing an order to modify, suspend, or revoke a license or an order prohibiting involvement in NRC-licensed activity (enforcement sanction) within the 5 year statutory period. The Statute of Limitations does not prevent the staff from issuing an NOV (without a civil penalty or other sanction) even if the underlying violation occurred more than 5 years earlier, or from issuing an order requiring an action needed to ensure compliance with existing requirements regarding protection of the public health and safety, promoting the common defense and security, or protecting the environment.

Question No: 181 Module 08: Enforcement

Ouestion

Do enforcement actions take into consideration the nature of the non-compliance?

Response

Potential noncompliances may be identified through NRC inspections, NRC investigations, allegations supported by an NRC inspection or investigation, licensee internal audits, licensee employee reports, or licensee self-disclosing events.

When an apparent significant safety or security issue is identified, the region engages the licensee to have it initiate immediate action to correct the condition if the public is likely to be endangered by continued operations or there is a concern involving the lack of integrity of those involved in licensed activities. The NRC can also issue a CAL or an immediately effective order to bring about immediate corrective action, if circumstances require that level of intervention. Based on the circumstances of the case, an expedited inspection report limited in scope to the issue may be prepared, or the Office of Investigation (OI) may provide preliminary information. When necessary, enforcement action may be taken before an inspection report is issued or a predecisional conference is held.

It is necessary to gather specific information about an apparent noncompliance so that the agency can make an informed decision on how to disposition it appropriately. When an apparent noncompliance is identified, the agency must do the following:

- -Determine whether a noncompliance has occurred (an event with safety consequences does not necessarily constitute a noncompliance).
- -Assess the safety significance.
- -Categorize the severity level (if appropriate).
- -Determine the appropriate enforcement action.

The information that is gathered is also used in the enforcement process to document the NRC's decisions; therefore, it must be complete and accurate.

The following questions serve as a guideline for gathering the information necessary to inform the enforcement process. The list should not be considered prescriptive, or all-encompassing.

- -What requirement or commitment was violated?
- -How was the requirement or commitment violated?
- -Who caused the requirement or commitment to be violated?
- When was the requirement or commitment violated?
- -How long did the noncompliance exist?
- -How, when, and by whom (licensee or NRC) was the violation discovered?
- -What is the apparent significance of the issue, for example, actual or potential consequences, potential for impacting regulatory process, was willfulness involved?
- -What information is necessary to complete the SDP (if applicable)?
- -What was the apparent cause?
- -What corrective actions have been taken or are planned to be taken (if known)?
- -Did the licensee place the issue in its corrective action program (if applicable)?
- Was the licensee required to report the violation and, if so, what was the applicable reporting requirement?
- -If a report was required, when was the report made to the NRC?

After the staff has determined that the noncompliance is a violation, the staff must assess the significance of the violation before determining how the violation should be dispositioned. The staff considers four specific factors when assessing significance:

(1) Actual Safety or Security Consequences

Actual safety or security consequences include an actual onsite or offsite release of radiation, onsite or offsite radiation exposure, an accidental criticality, core damage, loss of a significant safety barrier, loss of control of radioactive material, or a radiological emergency.

(2) Potential Safety or Security Consequences

Potential safety or security consequences include potential outcomes based on realistic and credible scenarios (i.e., the staff considers the likelihood that safety or security could have been negatively impacted under these scenarios). The NRC will use risk information wherever possible in assessing significance and assigning severity levels. A higher severity may be warranted for violations that have greater risk significance and a lower severity level may be appropriate for issues that have low risk significance. Duration is an appropriate consideration in assessing the significance of violations.

3) Impacting the Regulatory Process

The NRC considers the safety significance of noncompliances that may impact the NRC's ability to carry out its statutory mission. The agency is unable to use appropriate regulatory tools to address a noncompliance because the agency is unaware that the noncompliance exists. Examples of violations that impact the regulatory process include the failure to do the following: receive prior NRC approval for changes in licensed activities; notify the NRC of changes in licensed activities; perform 10 CFR 50.59 ("Changes, Tests and Experiments") analyses; provide the notice required by 10 CFR 150.20 ("Recognition of Agreement State Licenses"); meet the requirement associated with the change process provisions in 10 CFR 50.54(a) (involving quality assurance programs), 10 CFR 50.54(p) (involving safeguards plans), or 10 CFR 50.54(q) (involving emergency plans); or notify the NRC pursuant to the Commission's requirements.

In determining the significance of a violation that impacts the NRC's regulatory process, the NRC will consider the following: (a) the position and responsibilities of the person involved in the execution of licensed activities relative to those activities or the use of licensed materials, regardless of the individual's job title or whether the individual is working directly for the licensee or working for a contractor engaged in activities associated with licensed activities; (b) the significance of the underlying violation (i.e., when an issue is being considered for enforcement action because it impacts the NRC's regulatory process, it should first be reviewed on its own merits to ensure that its severity level is characterized appropriately given the significance of the particular violation); and (c) whether the failure actually impeded or influenced regulatory action or invalidated the licensing basis.

Unless otherwise categorized in the Supplements to the Enforcement Policy, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance and the circumstances surrounding the matter that should have been reported. The severity level of an untimely report, in contrast to no report, may or may not be reduced depending on the circumstances surrounding the matter (e.g., if the NRC had received the report in a timely manner, would the NRC actually have taken an action based on the report).

(4) Willfulness

Willful violations are by definition of particular concern to the Commission because its regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor.

Willful violations cannot be tolerated by either the Commission or a licensee.

Therefore, a violation involving willfulness may be considered more significant than the underlying noncompliance.

Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances of the violation in order to create a deterrent effect within the licensee's organization and contract support. The relative weight given to each of the following factors in arriving at the significance assessment will be dependent on the circumstances of the violation:

-The position and responsibilities of the person involved in the execution of licensed activities relative to those activities or the use of licensed materials. -Notwithstanding an individual's job title or whether the individual is working directly for the licensee or working for a contractor engaged in activities associated with licensed activities, several factors should be considered when determining the severity level of a willful violation, including: (1) whether the individual has the formal or informal authority to direct the actions of others, (2) whether the individual is, in fact, directing the actions of others, and (3) whether the individual used his or her position to facilitate the violation (e.g., providing incomplete or inaccurate information or suppressing audit findings).

-The significance of any underlying violation. Each issue being considered for enforcement action that includes willfulness should first be reviewed on its own merits to ensure that its severity level is characterized appropriately given the significance of the particular violation.

-The intent of the violator. Willfulness embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts that do not rise to the level of careless disregard (e.g., negligence or inadvertent clerical errors in a document submitted to the NRC).