

STC-17-036 Resolution of Comments (ML17186A134)
 Inspection Manual Chapter 2800 (ML17186A204)

Comment No.	Source	Section #	Comment	Added	Remarks
1	TX	Page 3, Section 03.13	<p>Does the NRC ever contact Licensees by email? Inspection Manual is written such that they only use a telephone to contact Licensee. If they use email they need to update these section:</p> <p>03.13 Telephonic Contacts. These are contacts, made by telephone and documented in the docket file, as well as in the Agencywide Documents Access and Management System (ADAMS), to determine the status of licensee activities, assess compliance of Priority T licensees [See Section 05.05], or to exchange information with the licensee. Examples of telephonic contacts include reminding a licensee that its license is near expiration, calling to determine whether there are sufficient licensee operations to conduct an onsite inspection, or calling to determine whether the licensee actively possesses licensed material. Telephonic contacts are not inspections.</p>	No	<p>Yes, the NRC does contact licensees by means other than telephone. The working group recognizes that this section needs to be updated to reflect modern technology. The working group will revisit this definition, as well as Priority T inspections in general, as part of Phase 2.</p>
2	TX	Page 4, Section 2800-05	<p>Does the NRC ever contact Licensees by email? Inspection Manual is written such that they only use a telephone to contact Licensee. If they use email they need to update these section:</p> <p>Telephonic contacts [See Section 05.05] are not inspections and are performed as resources permit.</p>	No	<p>Yes, the NRC does contact licensees by means other than telephone. The working group recognizes that this section needs to be updated to reflect modern technology. The working group will revisit this definition, as well as Priority T inspections in general, as part of Phase 2.</p>

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 Inspection Manual Chapter 2800 (ML17186A204)

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3	TX	Page 11, Section 05.01, (b)(5)(a)	<p>The following paragraph discusses the potential of looking at proprietary info. Should the manual also discuss the potential review of private public health information and the use of the HIPAA Privacy Rule during an inspection?</p> <p>When an inspection is likely to involve proprietary information, given the technical area or other considerations of inspection scope, the inspector should discuss with licensee management during the entrance meeting how the information will be handled during the inspection.</p>	Yes	The working group recognizes that inspectors may encounter other types of sensitive information beyond proprietary information. This section was revised to include several additional examples, based on this comment.
4	CO	N/A: General Comment	Changing the current 25 percent buffer to 50 percent for inspection timeliness. Colorado supports this change.	N/A	Acknowledged the comment.
5	CO	N/A: General Comment	Extending the initial inspection period if licensees are not in possession of licensed material. Colorado does not support this change. See CO comment #7.	No	The proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.
6	CO	N/A: General Comment	Allowing for extensions of inspection intervals based on good performance on a case-by-case basis. Colorado does not support this change and would not incorporate this into our program. See CO comment #11.	No	The proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.

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 Inspection Manual Chapter 2800 (ML17186A204)

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7	CO	Page 1, Section 03.02	Colorado believes that the one year time frame is beneficial even in the case that the licensee claims that they have not acquired materials within that time frame. A site visit and a face to face with the new licensee is helpful to get their programs started off on the right foot. Additionally, a site visit within that first year is an opportunity to verify their claims whether or not they have acquired materials.	No	The proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.
8	CO	Page 1, Section 03.03	This is a required part of our pre-licensing activities. For Colorado any change in security of Part 37 materials requires some type of verification that all security measures are in place and operable prior to authorizing any activity.	No	Acknowledged the comment. The working group recognizes that what were formerly called "initial security inspections" are part of the pre-licensing activities and are covered under other guidance documents. No changes were made as a result of this comment.

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9	CO	Page 16, Section 05.03	<p>It appears that this is shifting from 12 to 18 months for initial inspections. This is inconsistent with the time frames required for the inspection of a licensee who expands their program significantly or adds a modality. See 07.02b.</p> <p>a. Additionally Colorado believes that the visit in the twelve month period is appropriate and promotes a relationship with a new licensee resulting in better compliance right from the start. Colorado does not support this.</p> <p>b. Colorado appreciates that service providers may not possess materials but still take part in their authorized principal activity.</p> <p>c. Colorado is in favor of the idea of a standard license condition to require notification within 30 days of the receipt of material or initiation of principal activities for new licensees. Colorado would support this change and would likely incorporate this into our licensing program.</p>	No	<p>Regarding the perceived inconsistency between initial inspections and inspections of significantly expanded programs, the example was removed to provide greater flexibility in scheduling special inspections of significantly expanded program and leaving it to the discretion of the regulatory authority as the situation warrants.</p> <p>Regarding (a.), the proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.</p> <p>The working group acknowledges (b.) and (c.).</p>
10	CO	Page 20, Section 06.01	The overall inspection grace period remains no more than 1 year. Colorado supports this.	N/A	Acknowledged the comment.

STC-17-036 Resolution of Comments (ML17186A134)
 Inspection Manual Chapter 2800 (ML17186A204)

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11	CO	Page 23, Section 06.05	<p>Colorado would not likely see the need for this extension and as written it presents some particular problems:</p> <p>a. In general it seems like a lot of extra administrative work to extend an inspection period for an individual licensee.</p> <p>b. Specifically:</p> <p>i. 06.05: How is the grace period calculated for an inspection that is subject to an extension?</p> <p>ii. 06.05.a.4: It is unclear if this means working in other jurisdictions under reciprocity or this means the same parent entity working under a separate license elsewhere in the country. This may be difficult to determine either way.</p> <p>iii. Section 06.05.c: This would present the possibility of a bad actor causing the inspection to go past the grace period and be considered late as a result of a licensee's action and the inability to perform a reactive inspection upon short notice.</p>	Yes/No	<p>In response to (a), the proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.</p> <p>In response to (b)(i), the working group added a sentence to the end of the first paragraph of Section 06.05 to state that the scheduling window is not changed by an extension and is still based on the licensee's default inspection priority.</p> <p>In response to (b)(ii), no change was made to this revision as a result of this comment. Paragraph (a)(4) is another data point that may be considered in making a determination to extend based on high performance. It is not intended to cause a considerable effort to be undertaken to determine this. If the information is easily available, it should be considered in the determination.</p> <p>In response to (b)(iii), the working group revised this paragraph to allow more flexibility.</p>
12	CO	Page 24, Section 06.06	Colorado supports the changes made in this proposed section.	N/A	Acknowledged the comment.

STC-17-036 Resolution of Comments (ML17186A134)
 Inspection Manual Chapter 2800 (ML17186A204)

Comment No.	Source	Section #	Comment	Added	Remarks
13	CO	Page 25, Section 07.02 (b)	Seems to indicate that the manual still considers an addition of a modality (specifically 35.1000) to require an inspection within 12 months. Is this captured somewhere else? Seems inconsistent with the proposed change to the flexibility for a purely new licensee. What if a new licensee is a 35.1000 license? They get up to 18 months or more and an existing licensee only gets 12 months? That doesn't seem to be equitable nor sensible especially when considering one as an addition to an existing program (that may have no prior compliance issues) and a brand new licensee with no experience.	Yes	The example was removed to provide greater flexibility in scheduling special inspections of significantly expanded program and leaving it to the discretion of the regulatory authority as the situation warrants.
14	CO	Page 39, Section 11.01	The reference to the Special Inspection Code is unclear and not defined.	No	The working group will revisit this section as part of Phase 2.
15	VA	N/A: General Comment	Virginia does not support changing the current 25 percent buffer to 50 percent for inspection timeliness. This would open the possibility to unnecessary delays. 25% provides an ample opportunity for scheduling and inspections.	No	The proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.
16	VA	Page 1, Section 03.02	Virginia does not support extending the initial inspection period if licensees are not in possession of licensed material. The one year time frame is beneficial even in the case that the licensee claims that they have not acquired materials within that time frame. A site visit with the new licensee is helpful to ensure their programs are established appropriately. As such, a visit within that first year is an opportunity to verify their claims as to whether or not they have acquired materials.	No	The proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.

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 Inspection Manual Chapter 2800 (ML17186A204)

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17	VA	Page 16, Section 05.03	<p>This proposed change appears to introduce a shift for initial inspections from 12 to 18 months. This is inconsistent with the time frames required for the inspection of a licensee who expands their program significantly or adds a modality.</p> <p>a. A visit in the twelve month period is appropriate and promotes a relationship with a new licensee resulting in a better likelihood of compliance. Virginia does not support a change to an 18 month interval.</p> <p>b. Service providers may not possess materials but could still take part in their authorized principal activity.</p> <p>c. However, Virginia supports a standard license condition to require notification within 30 days of the receipt of material or initiation of principal activities for new licensees.</p>	No	<p>Regarding the perceived inconsistency between initial inspections and inspections of significantly expanded programs, the example was removed to provide greater flexibility in scheduling special inspections of significantly expanded program and leaving it to the discretion of the regulatory authority as the situation warrants.</p> <p>Regarding (a.), the proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.</p> <p>The working group acknowledges (b.) and (c.).</p>
18	VA	Page 20, Section 06.01	Virginia supports the overall inspection grace period of no more than 1 year.	N/A	Acknowledged the comment.

STC-17-036 Resolution of Comments (ML17186A134)
 Inspection Manual Chapter 2800 (ML17186A204)

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19	VA	Page 23, Section 06.05	<p>Virginia does not support allowing extensions of inspection intervals based on good performance on a case-by-case basis:</p> <p>a. Extending inspection periods for individual licensees will create a significant administrative and resource burden. Further, it is unclear as to how the grace period is to be calculated for an inspection that is subject to an extension.</p> <p>b. 06.05.a.4: It is unclear if this means working in other jurisdictions under reciprocity or this means the same parent entity working under a separate license elsewhere.</p> <p>c. 06.05.c: This would present the possibility of a bad actor causing the inspection to exceed the grace period and be considered late as a result of a licensee's action and the inability to perform a reactive inspection upon short notice.</p>	Yes	<p>In response to (a), the proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program. The working group added a sentence to the end of the first paragraph of Section 06.05 to state that the scheduling window is not changed by an extension and is still based on the licensee's default inspection priority.</p> <p>In response to (b), no change was made to this revision as a result of this comment. Paragraph (a)(4) is another data point that may be considered in making a determination to extend based on high performance. It is not intended to cause a considerable effort to be undertaken to determine this. If the information is easily available, it should be considered in the determination.</p> <p>In response to (c), the working group revised this paragraph to allow more flexibility.</p>

STC-17-036 Resolution of Comments (ML17186A134)
 Inspection Manual Chapter 2800 (ML17186A204)

Comment No.	Source	Section #	Comment	Added	Remarks
20	VA	Page 25, Section 07.02 (b)	This section appears to indicate that the manual still considers an addition of a modality (specifically 35.1000) to require an inspection within 12 months, which would be inconsistent with the proposed change to the flexibility for a new licensee. Would a new 35.1000 license allow up to 18 months or more and an existing licensee only 12 months? This seems neither equitable nor sensible when considering one as an addition to an existing program (that may have no prior compliance issues) compared to a new licensee with no experience.	Yes	The example was removed to provide greater flexibility in scheduling special inspections of significantly expanded program and leaving it to the discretion of the regulatory authority as the situation warrants.
21	VA	Page 39, Section 11.01	The reference to the Special Inspection Code is unclear and not defined.	No	The working group will revisit this section as part of Phase 2.

STC-17-036 Resolution of Comments (ML17186A134)
 Inspection Manual Chapter 2800 (ML17186A204)

Comment No.	Source	Section #	Comment	Added	Remarks
22	TX	Enclosure 1	<p>Enclosure 1 of the NRC Inspection Manual Chapter (IMC) 2800 assigns Priority Code 2 (inspection frequency every 2 years) for the Waste Disposal (Burial) for Commercial and Non Commercial facilities. This requirement is in conflict with the Table 1 of the IMC 2401 "NEAR –SURFACE LOW-LEVEL RADIOACTIVE WASTE DISPOSAL FACILITY INSPECTION PROGRAM" which requires annual inspections of the commercial Low-Level Radioactive Waste (LLRW) disposal facilities.</p> <p>It should be noted that the conflict between IMC 2401 and IMC 2800 was discussed with the NRC IMPEP Team during Texas Commission on Environmental Quality (TCEQ) Radiation Control Program review in February 2014. Also, in response to the IMPEP draft final report dated May 21, 2014, the TCEQ commented (Comment 3) on this issue in a letter dated June 20, 2014, addressed to Mr. Duncan White. In response to the TCEQ's comment, NRC stated (Response 3) "The designation of a two-year frequency for inspections of LLRW disposal facilities described in NRC Inspection Manual Chapter (IMC) 2800 is an error and will be corrected during next revision of IMC 2800." NRC further stated inspection of various activities at LLRW disposal facilities are to be inspected at an annual basis.</p> <p>To address this conflict, is the NRC considering to change the Priority Code for the commercial LLRW disposal facilities in IMC 2800 from 2 to 1 during Phase One (or Phase Two) revision of the IMC 2800?</p>	No	<p>This comment will be addressed in Phase 2 of the IMC 2800 revision. The working group will revisit the inspection priorities for all license types as part of Phase 2.</p>

STC-17-036 Resolution of Comments (ML17186A134)
 Inspection Manual Chapter 2800 (ML17186A204)

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23	AR	Page 1, Section 03.03	The Department recommends that the definition "Initial Security Inspection" be retained in this section. This assures that a clear definition is provided for the different types of inspections. The removal of this definition would make it appear that it has been devalued.	No	The working group recognizes that what were formerly called "initial security inspections" are part of the pre-licensing activities and are covered under other guidance documents. Removal of this definition is not intended to devalue onsite security reviews, but to defer to the appropriate licensing guidance and its definition of these reviews.
24	AR	Page 3, Section 03.13	<p>The Department recommends that the definition for telephonic contacts (Priority T) be consistent throughout the Inspection Manual 2800.</p> <p>Specifically, Item 03.13 states, "Telephonic contacts are not inspections."</p> <p>Whereas, Section 2800-5, Item 05.05 states, "This questionnaire should be completed, signed by the inspector, and placed in the docket file, and the 'next inspection date' data element in the LTS shall be changed to indicate the date of the next telephonic contact." It also states, "The inspector shall charge time to HRMS as direct inspection effort."</p> <p>Whereas, Section "List of Enclosures: Enclosure 1 – Inspection Priority Codes Assigned to Program Codes" lists Priority T Codes throughout the document.</p>	No	Telephonic contacts will be revisited during the Phase 2 revision of IMC 2800.

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 Inspection Manual Chapter 2800 (ML17186A204)

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25	AR	Page 16, Section 05.03	<p>In Item 05.03 proposed changes, it states in part, "initial inspections of a new license shall be announced and normally completed within 12 months of the date the new license was issued."</p> <p>Following, it states, "However, as described below, if the licensee has not possessed licensed materials or has not performed any principle activities, the initial inspection may be rescheduled to within 18 months of license issuance."</p> <p>The Department recommends that the inspection time frame for initial inspections remain at the current 12 month frequency. This would allow consistency in procedures and a proper analysis of operations, security, health, and safety for radioactive material storage, transportation, and uses.</p>	No	<p>The proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.</p>
26	AR	Page 21, Section 06.01	<p>In Item 06.01 proposed changes, it states, "Inspection of licensees in Priority Codes 1 and 2 may vary around their due date by \pm 50 percent." The Department concurs.</p>	No	<p>Acknowledged the comment.</p>
27	AR	Page 21, Section 06.03	<p>Item 06.03 states, "If escalated enforcement action has taken place for a particular licensee, a special inspection that focuses on Severity Level III or above violation(s) shall be scheduled and conducted within 6 months of the issuance of the escalated enforcement action (Severity Level III or above)."</p> <p>The Department recommends that the special inspection, as described above, be scheduled and conducted within 12 months of the issuance of the escalated enforcement action. The Department proposes this change to allow reasonable time for the licensee to fully implement its corrective actions and to provide demonstrations of sustained performance.</p>	Yes	<p>The working group discussed the requirement to conduct enforcement followup inspections and agreed that efficiencies can be gained by extending the due date to 12 months from issuance of the escalated action without compromising public health and safety. The appropriate regulatory authority can always elect to conduct a followup sooner as the situation warrants.</p>

STC-17-036 Resolution of Comments (ML17186A134)
 Inspection Manual Chapter 2800 (ML17186A204)

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28	OAS	N/A: General Comment	The OAS supports changing the current 25 percent buffer to 50 percent for inspection timeliness.	N/A	Acknowledged the comment.
29	OAS	N/A: General Comment	The OAS supports extending the initial inspection period if licensees are not in possession of licensed material, however, this is inconsistent with the time frames required for the inspection of a licensee who expands their program significantly or adds a modality. The same inspection period extension should be applied to these license categories if no material is possessed. The OAS agrees with a standard license condition on new licenses requiring them to notify the State upon initial receipt of radioactive material.	Yes	The example was removed to provide greater flexibility in scheduling special inspections of significantly expanded program and leaving it to the discretion of the regulatory authority as the situation warrants.
30	OAS	N/A: General Comment	Some states have expressed concern with Priority T licenses because it is believed that all specific licensees should have onsite inspections.	No	Telephonic contacts will be revisited during the Phase 2 revision of IMC 2800.
31	OAS	N/A: General Comment	The OAS believes that any change in security of Part 37 materials requires some type of verification that all security measures are in place and operable prior to authorizing any activity.	No	No changes were made to the revision as a result of this comment. This comment is more applicable to the pre-licensing guidance.
32	OAS	N/A: General Comment	The OAS does not support allowing for extensions of inspection intervals based on good performance on a case-by-case basis. It would seem to create more problems, both administratively and technically, then it solves. The turnover of personnel other than the Radiation Safety Officer affects licensee performance.	No	The proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.

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 Inspection Manual Chapter 2800 (ML17186A204)

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33	NY	Page 16, Section 05.03	Agree with the provision to defer an initial inspection if it can be documented that a new licensee has not possessed licensed material or has not engaged in principal activities, except for a licensee that is authorized to possess a category 2 or greater quantity and which was not subject to a pre-licensing visit. In general, a licensee must be engaged in principal activities for the regulator to conduct a performance based inspection. Until such time that a licensee possesses material, the regulatory process of licensing provided sufficient oversight. The change will allow for better use of staff resources without a reduction in health and safety.	N/A	The proposed changes to IMC 2800 are intended to allow flexibilities in the inspection program to gain efficiencies without diminishing the protection of public health and safety. The proposed changes provide options, not impose new requirements, for NRC and the Agreement States to realize potential efficiency gains without compromising public health and safety. Agreement States have the flexibility to incorporate these changes into their respective inspection programs as it best suits their program.
34	NY	Page 20, Section 06.01	Suggest editing the first sentence" "Routine inspection should be conducted as close to their due date as possible." to "Inspectors should plan to conduct routine inspections close to the due date." The reason is that it seems contradictory to state that the inspection should be done as close to the due date as possible while also allowing for a 50% window. We agree with the revisions to the inspection scheduling windows for the routine inspections of priorities 1-3, 5, and T. The change in the scheduling window will allow for better use of staff resources without a reduction in health and safety.	Yes	Changes made, as requested.

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 Inspection Manual Chapter 2800 (ML17186A204)

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35	NY	Page 23, Section 06.05	Agree with the provision to extend the inspection interval on a case by case basis, and the example criteria/guidance. Management involvement should serve to ensure that an extension is appropriate. However, we suggest dropping “high performing licensee” from the last sentence of 06.05a.4. The section is applicable to a “good performer” as indicated in the first sentence. We should not introduce a new level of “high performing licensee” later in that section. Also, we suggest that the manual should indicate of the licensee should be informed of an extension between the next inspection or not. The proposed Extension of change will allow for better use of staff resources without a reduction in a health and safety, and will present less of a regulatory burden for a good performing licensees.	Yes	Changes made, as requested. This section was revised based on another comment to ensure consistent use of terminology throughout; however, the occurrence as noted in this comment is not necessary to convey the intended message and has been removed.
36	NY	Page 24, Section 06.06	Agree with the provision to extend the inspection interval for licensees with a good performance history. This change will allow for better use of staff resources without a reduction in health and safety, and will present less of a regulatory burden for good performing licensees.	N/A	Acknowledged the comment.
37	NY	Page 26, Section 07.03	This section indicated that the details for the percentage of reciprocity licensees to be inspected each year are in IMC 1220. We suggest that the 20% target for priority 1-3 reciprocity inspections should be stated in IMC 2800, and the reference to IMC 1220 should remain.	No	This comment will be addressed in Phase 2 of the IMC 2800 revision.