Comment Resolution for the New York
Draft IMPEP Report - REVISED

Comment 1: Page 4

Page 4, last paragraph, first sentence and throughout: change "Radiation Sites Section" to "Radiological Sites Section.

Response 1:

Thank you for the correction. The corresponding edits were made.

Comment 2: Page 4

Page 4, last paragraph: change "Positions are almost always eliminated once they are vacated" to "Positions are often eliminated…

Response 2:
Thank you for the comment. The edit was accepted.

Comment 3: Page 5

Page 5, second sentence, states "New York State employee travel restrictions make it difficult for this employee to travel to Albany for training." These travel restrictions have been eased by that regional employee's administration; the primary difficulty is the long distance (over 8 hours round trip) and overnight hotel costs for this employee to travel to Albany to obtain training with the radiation program staff, all of whom are located in the Albany Central Office.

Response 3:
Thank you for the comment. The comment was resolved by changing report text to read "Travel logistics and State travel restrictions make it difficult for this employee to travel to the Albany central office for training."

Comment 4: Page 12

Page 12, 4.0, second sentence contains a typo: "The NRC's Agreement with New York does not relinquish regulatory authority for a r uranium recovery program…"

Response 4:

Thank you for the correction. The corresponding edit was made.

Comment 5: Page

Page 12, 4.1.1, first paragraph, next to last sentence states "These regulations also cover the transportation and manifestation of LLRW shipments…" Change the word "manifestation" to "manifesting."

Response 5:

Thank you for the correction. The corresponding edit was made.

Comment 6: Page 16

Page 16, 4.1.2: the web link/page name provided appears to include a typo. The stated link is “rss regamendents.html” – was it meant to say “rss regamendments.html”?

Response 6:

Thank you for the comment. A correction was made. The correct link is http://nrc-stp.ornl.gov/rss_regamendents.html

Comment 7: Page 18

Page 18, second paragraph, change “the State-Licensed Disposal Area (SDA)” to “the State-licensed Disposal Area (SDA).” Although this may appear to be a minor correction, it is important to prevent migration of names and terms related to this site.

Response 7:

Thank you for the correction. The corresponding edit was made.

Comment 8: Page 18

Page 18, fourth paragraph, first sentence, insert the words “Part 380” between the words “one” and “permit.” This clarification is necessary because NYSERDA also holds non-radiological DEC permits for the SDA.

Response 8:

Thank you for the clarification. The corresponding edit was made.

Comment 9: Page 18

Page 18, fourth paragraph: change “The NYSERDA also holds a radioactive materials license from DOH for the West Valley Site” to “NYSERDA also holds a radioactive materials license from the DOH for the SDA.” This clarification is needed because NYSERDA does not hold a DOH license for the whole 3,300 acres of the West Valley Site, just for the SDA.

Response 9:

Thank you for the clarification. The corresponding edit was made.

Comment 10: Page 19

Page 19, first paragraph states "…Cornell operates a groundwater treatment system for non-radioactive contaminants." Following "contaminants," add "that collects and discharges minute amounts of radionuclides incidental to the non-radioactive treatment system. Those radioactive discharges are regulated by a substantive Part 380 discharge permit."

Response 10:

Thank you for the comment. The requested edit was made.

Comment 11: Page 19

Page 19, first paragraph also states "DEC plans to issue a substituent Part 380 permit before the remedial activates by the consent order have ended." Reword that sentence to instead state "DEC plans to issue a substantive Part 380 permit for ongoing monitoring and maintenance of the RDS before the Consent Order is terminated. When the Consent Order is terminated, any substantive permits issued under the Order will convert to stand-alone Part 380 permits."

Response 11:

Thank you for the comment. The requested edit was made.

Comment 12: Page 19

Page 19, 4.3.2, second paragraph: change the terms "license" and "licensee" to "permit" and "permittee." This clarification is needed because DEC issues permits, not licenses.

Response 12:

Thank you for your correction. The corresponding edits were made.

Comment 13: Page 19

Page 19, 4.3.2, second paragraph also refers to "pre-operational environmental monitoring." This is not an accurate statement, as the site is in an interim closure status; ongoing environmental sampling would therefore not be considered to be pre-operational.

Response 13:

Thank you for the clarification. "Pre-operational" was removed from the report text.

Comment 14: Page 20

Page 20, 4.3.3, third paragraph, second sentence: refers to a "NYSERDA-SLD Area at West Valley 2011 Annual Report." Correct this reference to refer to the "NYSERDA State-licensed Disposal Area (SDA)."

Response 14:

Thank you for the correction. The requested edit was made.

Comment 15: Page 20

Page 20, fourth paragraph: change the term “licensing” to “permitting.”

Response 15:

Thank you for the correction. The corresponding edit was made.

Comment 16: Page 22

Page 22, recommendation 4 states “The 2006 IMPEP review team recommended that DOH, NYC, DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 2.0, Open recommendation from the 2006, 2011, 2014 IMPEP reviews).” That paragraph needs several corrections, and should be reworded to state “The 2014 IMPEP review team recommends that DOH and DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 2.0, Open recommendation from the 2011 IMPEP review).

Response 16:

Thank you for your comment. The IMPEP team re-evaluated its reason for keeping the recommendation open and will recommend closing the recommendation to the Management Review Board. Each NY agency had developed and implemented an action plan as directed by the recommendation. The NYC agency was able to clear its backlog, but due to an arduous rulemaking process for both DOH and DEC, these agencies were not able to clear their backlog of overdue regulations. The IMPEP team determined that each agency is cognizant of the requirements to adopt compatible rules or use legally binding requirement within 3 years of the NRC’s effective date and each agency should address rules coming due proactively. (See also Comment/Response 33)

Comment 17:

The org charts for both NYS DOH Center for Environmental Health and our Bureau are outdate (not sure how that happened). I’ll send you updated charts.

Response 17:

Thank you for your sending current organization charts for DOH. The report will be update for these charts.

Comment 18:

Introduction, 3rd paragraph. Last paragraph, 3 rd sentence - It is unclear what you intend to convey with the word "utilization". If you delete that word then the sentence will be clear and accurate.

Response 18:

Thank you for the comment. "Utilization" was removed from report text.

Comment 19: Page 8

3.3 page 8, 3 rd paragraph – instrumentation. We believe the word "adequate" in the first sentence should be replaced with "ample". Adequate conveys have meet a minimum standard. Also the ion chamber should be changed to pressurized ion chamber and the portable multi-channel analyzers should indicate both HPGe as well as NaI types. Also the latter only effective for photons and they are not used to analyze wipes. DOH utilizes the Department's Wadsworth Center, Laboratory of Inorganic and Nuclear Chemistry for analysis of samples, including wipe, for routine inspections as well as for incident response.

Response 19:

Thank you for your insight. The comment was accepted in part. "Ample" replaced "adequate." This instrumentation discussion section under Technical Quality of Inspection addresses the types of instrumentation available for the New York Agreement State Program (i.e., the Program) as a whole and does not list the specific functionality of the available instrumentation. Therefore, the clarification on specific ion chambers and multi-channel analyzers available to DOH was not added to the report.

Comment 20: Page 8

3.4, page 8, first paragraph, 3rd sentence – "The casework was also reviewed for timeliness Please indicate where in SA-104, or elsewhere, where a timeliness standard exists.

Response 20:

Thank you for the comment. Timeliness is implied in Section III of SA-104, *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions.* The procedure states that "the evaluation of technical quality includes not only the review of the application and completed actions, but also an examination of any renewals that have been pending for more than a year, because the failure to act on such requests may have health and safety implications." No change was made to the report in response to the comment.

Comment 21: Page 9

Page 9, 1st paragraph: 7+2+3=12, not 9.

Response 21:

Thank you for the comment. A report correction was made.

Comment 22:

Second paragraph, 1st sentence – It should be noted in the report that DOH requires original documents before a license action is approved. (an email or fax may certainly start the process.)

Response 22:

Thank you for the comment. The requested edit was added to the report text.

Comment 23:

Last sentence is incorrect. The Section Chief, Director and Assistant Director have signature authority and have signed numerous licensing actions for this IMPEP review period.

Response 23:

Thank you for the correction. The report was changed to reflect the signature authority of the Director and Assistant Director.

Comment 24:

4th sentence. "Routinely staff used electronic mail and phone calls to follow up with deficiency notices." For DOH, follow up requests are fully documented in the license files, and this should be noted.

Response 24:

Thank you for the comment. The requested edit was added to the report text on page 10 first paragraph.

Comment 25: Page 14-15

Overdue regs. Pages 14-15. The first one listed as overdue for DOH on page 15 should be listed under the prior listing that is on page 14 –Partial Amendments (10 CFR 35 only). Also it is unclear why the 4 (now 5 with the above correction) are listed again on page 15 as well.

Response 25:

Thank you for your comment. The report reflects action taken on rule adoption during the review period. In addition, the Part 35 regulations of the rule (RATS ID 1995–7) referenced in this comment were superseded by RATS IDs 2002-2 and 2005-2 which were submitted by DOH and acknowledged as partial amendments in this report. The Part 20 provisions of

this rule still need to be adopted; hence, the reason it was listed under the overdue amendments. For those RATS IDs listed as both partial and overdue, a note was added in the report to indicate the overdue list includes the four partial amendments because regulations in other Parts still need to be promulgated to complete the rule. The amendments listed as partially complete was added by the IMPEP team to show the progress DOH has made with compatibility requirements since full credit cannot be given for these amendments until the other regulation Parts have been addressed as final rules or legally binding requirements. No other changes were made to the report in regard this comment. The IMPEP report is consistent with DOH's current SRS sheet.

Comment 26:

File No.: 2
Licensee: Daniel Amen, M.D./Amen Clinics Inc. License No: 91-3475-01
Type of Action: Amendment No.: 01
Date Issued: License Reviewer: I. S.
Comment: The reviewer improperly added an individual as an AU and RSO to the license. The proposed AU and RSO did not meet the qualification requirements in accordance with 175.103(j)(5), and 175.103(j)(1), respectively.

DOHMH Comment: The NRC should remove its deficiency finding regarding the qualification of the authorized user (AU) for License No: 91-3475-01. The AU meets the qualifications of 10 CFR Part 35.200 for the activity performed under the license. The AU submitted NRC form 313A (AUD) presenting the necessary classroom, laboratory and supervised work experience and training, which documented 80 hours of classroom and laboratory training (radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use). The AU also presented 620 hours of work experience under the supervision of Dr. Daniel Amen for all aspects of section b. of NRC form 313A (AUD), except for those relating to eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies. DOHMH believes that the credentials and training/work experience presented are sufficient to approve the AU for activities allowed under License No: 91-3475-01 and in accordance with 10 CFR Part 35.200. Attached are copies of NRC form 313A (AUD) the AU submitted to DOHMH, the certification of 80 hours of certified training, and License No: 91-3475-01.

Response 26:

Thank you for your insight. The documentation provided to address this comment was the same documents reviewed by the IMPEP team. The individual did not meet the full qualifications under NRC regulation 10 CFR 35.290 or the equivalent New York state regulation 175.103(j)(5) because the individual did not have experience related to eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs. The fact that the individual did not meet the full training and experience as outlined in the regulation and documented in the NRC Form 313 was never addressed by the reviewer. There was no documentation to show that the individual requested an exemption to this regulation, and there was no documentation to show DOHM had decided to exempt the individual from this regulation.

However, during the Management Review Board (MRB) meeting the concerns over the AU's qualifications were resolved. The performance concern was removed from the casework review.

Comment 27:

File No.: 8
Licensee: Montefiore Medical Center License No.: 75-2885-01
Type of Action: Amendment No.: 38 & 39
Date Issued: in 2012 License Reviewer: D.H.
Comment:
(a)The license did not have an issuance date.
(b)The reviewer improperly added new material to the license. License amendment was not properly supported by information in the file.
(c) The same material was removed in the next with no letter, correspondence, or other supporting documentation that would explain the removal of the material from the license.

DOHMH Comment: The NRC should withdraw the three deficiencies identified from its review of Montefiore Medical Center License No.: 75-2885-0. Each of the three findings is not supported by the information in licensing files for License No.: 75-2885-01. Amendment number 38 and 39 were signed and dated March 5, 2012 and November 20, 2012 respectively. The file contains the correspondence requesting the proposed change and the documentation that was submitted in support of the requested amendments. Attached are the letters and the supporting documentation Montefiore Medical Center submitted for Amendments 38 & 39 for License No.: 75-2885-01 and the signed/dated licenses. In light of the information provided, the NRC should withdraw the deficiencies related to its review of License No.: 75-2885-01.

Response 27:

Thank you for your insight. The documentation provided to support this comment is for Technetium-99 which is not the radionuclide the IMPEP team was referencing in items b and c above. The radionuclide added and removed inappropriately to license amendment 38 and 39, respectively was Yttrium-90 (Y-90) Thera-Spheres. The documents reviewed for this finding were in the licensing folder provided to the IMPEP team. The licensee is currently authorized for Y-90 Microspheres; however, the request to add Y-90 Thera-Spheres must be accompanied by additional information regarding training and experience according to guidance from the manufacturer because the delivery process to the patient is significantly different for Y-90 Microspheres and Y-90 Thera-Spheres. In the documents reviewed by the IMPEP team, the Y-90 Thera-Spheres was added based upon a one page request without documentation to outline necessary training and experience. The amendment on file was not dated. The staff was interviewed at the time of the review to try to determine an issuance date and the staff could not find a dated license and could not determine when the amendment was issued. Subsequently, Y-90 Thera-Sphere was removed in amendment 39 and thereafter with no letter, correspondence, or other supporting documentation that would explain the removal of the material from the license. Amendment 39 did not have an issuance date. However, during the MRB, the status of amendments #38 and #39 were resolved. The signed and dated copies of these

amendments did not authorize Y-90 Thera-Shperes. This concern was removed from the casework review.

Comment 28:

File No.: 10
Licensee: NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05
Type of Action: Amendment No.: 15
Date Issued: 03/03/14 License Reviewer: I. S.
Comment: The reviewer improperly added an individual as an RSO to the license. There was no supporting documentation to show the individual had received or was going to receive training regarding the radiation safety aspects of the gamma knife.

DOHMH Comment: The NRC should withdraw the deficiency finding that the RSO for NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05 was improperly added to the license without supporting documentation. This statement is incorrect. The file reviewed by NRC included a copy of License No.: 75-2878-05. This license file includes Form 313A (RSO) documenting the RSO's compliance with all aspect of the training and education requirements found at 10 CFR Part 35.600 (remote afterloader, teletherapy, and gamma stereotactic radiosurgery). The RSO had previously submitted the same NRC Preceptor Attestation Form 313A (RSO) to be added to NRC License # 08-30577-01. A copy of the NRC Preceptor Attestation Form 313A (RSO) submitted in support of being added to and the NRC License 08-30577-01 and License No.: 75-2878-05 is attached.

Rather than there being no supporting documentation supporting the decision to add the RSO to NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05, the file contained appropriate reference to the related approvals made by DOHMH documenting the qualifications and education and training of the individual to meet all aspects of 10 CFR Part 35.600. Accordingly, the NRC should withdraw this finding.

Response 28:

Thank you for your insight. The documents submitted to support the comment was the same set of documents reviewed by the IMPEP team. The documentation submitted to add the RSO to the NY Presbyterian Hospital/Columbia University Medical Center was deficient. The IMPEP review team recognized the proposed RSO was listed on a broad scope license for a facility that has a self-shielded irradiator and High Dose Radiation Unit. However, the NY Presbyterian Hospital/Columbia University Medical Center possesses a gamma knife. There was no supporting documentation to show the individual had received or was going to receive training regarding the radiation safety aspects of the gamma knife. In addition, there was no supporting document (i.e., copy of agreement state license) to show the individuals that served as a preceptor were qualified to do so. Furthermore, there is no documentation to show what type of gamma stereotactic radiosurgery the proposed RSO received his training and experience. In order to be added to the license, the reviewer should have ensured the individual had received training in the radiation safety, regulatory issues, and emergency procedures for the Perfexion™ gamma stereotactic radiosurgery unit. If the individual already has RSO responsibilities for a gamma stereotactic radiosurgery unit, in

accordance with 10 CFR 35.50(e), the training must also include instruction on the differences in the radiation safety, regulatory issues, and emergency procedures of the Perfexion™ unit and other gamma stereotactic radiosurgery units for which the individual has RSO responsibility. This training requirement may be satisfied by completing training that is provided by the Perfexion™ vendor, or supervised by an individual (RSO or AMP or AU) that is authorized for the Perfexion™ unit. The individual should complete or commit to complete supplemental hands-on radiation safety and emergency procedures training on an operational Perfexion™ unit before first use of the unit for patient treatment; AND for an RSO on a license authorized for the 10 CFR 35.600 medical use of a gamma stereotactic radiosurgery unit, documentation that the RSO has satisfactorily completed the above training and completed or provided documentation of a commitment to complete the supplemental hands-on training. No change to the report was made.

Comment 29:

File No.: 11
Licensee: Bhumi, Sarat License No.: 91-3342-01Type of Action: Renewal Amendment No.: 3
Date Issued: 07/03/12 License Reviewer: D. H.
Comment: Review did not demonstrate a thorough analysis of the licensee's inspection and enforcement history. The license reviewer did not adhere to the applicable and current guidance for this review.

DOHMH Comment: The NRC should remove its deficiency finding claiming that the review did not demonstrate a thorough analysis of the licensee's inspection and enforcement history. The licensing file includes the relevant inspections and enforcement actions taken regarding License No.: 91-3342-01. Multiple inspection findings and reports are included in the licensing action file. A copy of the last inspection report is attached. The facility was found in full compliance. While the primary contact for License No.: 91-3342-01 changed over time, which may have resulted in some confusion for the NRC review team, all of the regulatory and inspection activity in the file relates to License No.: 91-3342-01.

Response 29:

Thank you for your insight. The IMPEP team recognizes that documentation regarding the inspection of facilities was thorough and present in the inspection folder. The availability of these files was not the issue of the finding. At the time of the IMPEP review, there was no documentation to show the license reviewer performed a thorough analysis of the licensee's inspection files and the enforcement history. In addition, the same finding was identified in File No. 13 of Appendix D. No change was made to the report.

Comment 30:

Comment on Status of Regulatory Actions Coming Due:

Advance Notification to Native American tribes of Transportation of Certain Types of Nuclear Waste, RATS ID 2012-2, (Due date for State Adoption – 08/06/15) deals with advance notification to governor or Native American tribes of transportation of certain types of nuclear waste and irradiated reactor fuel. This would not apply to DOHMH.

Technical Corrections - Parts 30, 34, 40, and 71, RATS ID 2012-3, deals with requirements for industrial radiography and uranium mills. This would not apply to DOHMH.

Requirements for Distribution of Byproduct Material, RATS ID 2012-4, (Due date for State Adoption 10/23/15), deals with manufacture and distribution of commercial and industrial devices containing byproduct material, and is not regulated by DOHMH

DOHMH is actively evaluating the ability to "cite by reference" to adopt regulatory standards established by the NRC that are not addressed in the New York City Health Code. DOHMH is hopeful that Physical Protection of Byproduct Material, New Part 37 RATS ID 2013, (Due date for State Adoption 03/19/16) will be implemented using "cite by reference"

Response 30:

Thank you for your comment. In response, the State Regulation Status sheet for DOHMH was updated for RATS ID 2012-4 to indicate the rule does not apply to DOHMH. Applicability of RATS ID 2012-2 and 2012-3 require further assessment by DOHMH. Both rules impact transportation requirements (Part 71). In 2009, DOHMH promulgated Part 71 rules. Therefore, the Part 71 rule components may apply to DOHMH. There are no corresponding report changes as a result of this comment.

Comment 31:

NRC Recommendation One: This recommendation should be removed. As stated on page four of the draft IMPEP report, "the materials inspectors were fully qualified and the license reviewers were fully qualified and have full signatory authority for licensing actions." The NRC has applied compatibility "C" to IMC 1248 and cannot require that an Agreement Program mirror the administrative approach used by the NRC to the meet the performance goals of Technical Staffing and Training. In Section 3.1 the NRC did not identify a specific deficiency or inconsistency in the technical qualifications or training of qualified staff, how non-qualified staff are being trained to perform material inspection and licensing activity or how training is documented. It is important for IMPEP teams to use consistent measures between reviews. The procedures used by DOHMH for training and qualifying staff have not changed since the previous IMPEP, which did not make a recommendation. Further, DOHMH significantly increased its utilization of NRC sponsored training for staff that has been qualified and those being trained to be qualified since the last IMPEP. These efforts are not reflected in the IMPEP report and represent important improvements in the technical training and knowledge of the DOHMH staff since the last IMPEP.

If the NRC believes the IMPEP report is the correct forum to provide DOHMH direction regarding how it administers its program unrelated to a deficiency finding to meet the performance standards for technical staffing and training, DOHMH recommends that this recommendation be revised as a suggestion in the draft report that DOHMH consider incorporating aspects of IMC 1248 or other best practices it is aware. Specific examples of sections of IMC 1248 or other best practices should be provided. If suggested improvement to program administration unrelated to a deficiency finding is best addressed in another forum, DOHMH would welcome a thoughtful discussion regarding ways it may improve its administration of the program.

Response 31:

Thank you for your insight. However, the IMPEP team does not agree and stands by its recommendation. Qualification journals are designated as Compatibility Category C. Program elements with a Compatibility Category C designation need to contain the essential objectives of the NRC regulations. The NYC's training document provided to the IMPEP team is not consistent with IMC 1248. NYC has staff going through the qualification process and the qualification process used by NYC should reflect current standards.

Comment 32:

NRC Recommendation 3: The NRC review team found deficiencies with six licensing actions taken by DOHMH. Based on the documentation in licensing files and attached to these comments, the NRC findings were made in error for File 8, File 10 and File 11. A portion of the finding for File 1 was made incorrectly, as the AU met applicable qualifications. The program agrees that the RSO did not fully meet the qualification criteria. File 12 regarding the lack of a letter requesting cancelation of a minor license represents an administrative error rather than an indication of consistent errors in documentation or the technical sufficiency of the reviewer, who has since retired. While DOHMH agrees that File 13 represented a substantive lapse among the files reviewed, as discussed during the IMPEP, no public health risks were associated with improper renewal of this licensing action.

Considering that four of the six files with deficiency findings were made either fully or partially in error, the remaining deficiencies do not indicate that there is a systemic failing in the thoroughness and/or quality of the licensing activity performed by the two staff that is performing this role currently for DOHMH. Nothing in the records reviewed suggests that the NRC has identified systemic deficiencies in program administration that warrants specific corrective actions in administration of the program to be dictated by the NRC and/or the ability of DOHMH to conform to the technical staffing and quality of licensing compatibility requirements. Accordingly, DOHMH requests that recommendation 3 be removed. If the NRC believes it is necessary keep a portion of Recommendation 3, that should be limited to a request that DOHMH document that the errors identified have been addressed.

If the NRC believes that the IMPEP report is the proper forum to provide suggestions for how DOHMH could improve the administration of its program, those suggested improvements should be made in the body of the text and not as part of a formal recommendation requiring the program to present its actions to the NRC for review and acceptance at the next IMPEP.

Response 32:

Thank you for your insight. However, the IMPEP team does not agree and stands by its recommendation. The noted deficiencies were not changed as a result of the submitted documentation. See the response to Comments 26–29. The recommendation focuses on underlying the cause of the licensing quality issues and intends to promote improvement.

Comment 33:

Recommendation Four: New York City should be removed from this recommendation since its regulatory authorities are compatible with NRC and no regulatory actions are overdue.

Response 33

Thank you for your comment. The IMPEP team re-evaluated its reason for keeping the recommendation open and will recommend to the Management Review Board that this performance recommendation be closed. Each NY agency had developed and implemented an action plan as directed by the recommendation. The NYC agency was able to clear its backlog, but due to an arduous rulemaking process for both DOH and DEC, these agencies were not able to clear their backlog of overdue regulations. The IMPEP team determined that each agency is cognizant of the requirements to adopt compatible rules or use legally binding requirement within 3 years of the NRC's effective date and each agency should address rules coming due proactively. (See also Comment/Response 16).