

**2015 ALABAMA IMPEP**  
**Comment Resolution for the July 1, 2015, letter from Alabama (ML15197A419)**  
**regarding the June 11, 2015, draft IMPEP report**

**Alabama Comment 1**

**1.0 Introduction**

Fourth paragraph - The date for returning the questionnaire should be March 5, 2015, not April 28, 2015.

**NRC Response**

The review team agrees with the comment. The State returned the questionnaire by e-mail to the team leader on March 5, 2015. The date in the report was changed to reflect this. The document was not placed into ADAMS until April 28, 2015, which was the date originally used in the report.

**Alabama Comment 2**

**3.1 c. Evaluation**

- (a) Please note that while our current written training policy may not be equivalent to IMC 1248, it was found to be adequate and compatible during the 2010 IMPEP review. I believe this should be noted in the report.
- (b) The use of the word "formalized" is subjective, given the "formalized" training program we had in 2010 was found adequate and compatible, I request that the use of the term "formalized" be removed.

Alternative wording :

The review team determined that during the review period the State did not fully meet performance indicator objective listed 3.1.a concerning the State's qualification program. Alabama hired two technical staff as inspectors during the review period and transitioned an existing technical staff member into a license reviewer role. The State had not hired or trained technical staff for approximately seven years so there was no previous focus on updating Alabama Policy No. 417 "Summary of Basic and Specialized Training Requirements for Staff Working in the Agreement States Program in the Division of Radiation Control" which was put into place on October 20, 1997. This policy ~~is less formalized with undocumented~~ **does not require documented** training qualification for both the license reviewer and inspectors and lacks ~~the~~ **a** 24 hour refresher training criteria for existing qualified staff. **While this**

training policy was found adequate and compatible during the 2010 IMPEP review, it is not considered equivalent to NRC's IMC 1248. The review team attributed several performance issues discussed under the indicators Technical Quality of Inspections and Technical Quality of Licensing Actions to the lack of a formalized training policy equivalent to IMC 1248. The review team recommends that the State: (1) create a formal training qualification program equivalent to IMC 1248 and apply it to staff going through the qualification process; (2) require 24 hours of refresher training for currently qualified staff; and (3) reevaluate the qualifications of the two newest inspection staff to determine if additional training is needed.

### **NRC Response**

The review team agrees with the comment in part:

- (a) The NRC issued a revised training manual (MC 1248) in April 2013, which was due for adoption by the Agreement States in October 2013. The previous IMPEP team's review of Alabama's procedures is not valid for this review since the previous procedure was equivocal to MC 1246 and not to MC 1248. Since AL was required to adopt an equivalent training manual to MC 1248 (see FSME-13-043) the review team evaluated Alabama's procedures against MC 1248. Therefore it should not be noted in the report that the procedure was found adequate and compatible in 2010 as it has no bearing on this review period.
- (b) The review team understands Alabama's disagreement with the use of the word "formalized," and will remove it from the IMPEP report. The review team disagrees with the alternative wording provided by Alabama in their response. The review team has changed 3.1.c to read as follows:

The review team determined that during the review period the State did not fully meet performance indicator objective listed 3.1.a concerning the State's qualification program. Alabama hired two technical staff as inspectors during the review period and transitioned an existing technical staff member into a license reviewer role. The State had not hired or trained technical staff for approximately seven years so there was no previous focus on updating Alabama Policy No. 417 "Summary of Basic and Specialized Training Requirements for Staff Working in the Agreement States Program in the Division of Radiation Control" which was put into place on October 20, 1997. This policy is not equivalent to IMC 1248, does not require the training qualification to be documented for both license reviewers, and inspectors and lacks the 24 hour refresher training criteria for existing qualified staff. The review team attributed several performance issues discussed under the indicators Technical Quality of Inspections and Technical Quality of Licensing Actions to the lack of documented training for qualification resulting from the Program's procedure not being equivalent to IMC 1248, a lack of knowledge of the training procedure by the new staff, and a lack of understanding on the expectation of how to

become fully qualified. The review team recommends that the State: (1) create a formal training qualification program equivalent to IMC 1248 and apply it to staff going through the qualification process; (2) require 24 hours of refresher training for currently qualified staff; and (3) reevaluate the qualifications of the two newest inspection staff to determine if additional training is needed.

### **Alabama Comment 3**

#### **3.1 d. Result**

Remove the term “formalized” in the first paragraph... “The review team determined that the root cause of the performance issues is the lack of an updated ~~and formalized~~ training policy.”

Please note that we have developed , and have begun using , a revised training policy (see Attachment 1). We have also performed in-house and field retraining of our two new inspectors. They were then accompanied by their supervisor . After he completed his review of their performance, he requested that they be accompanied by either the office director or assistant director. This has been accomplished for two types of inspections (industrial measuring systems and basic medical).

### **NRC Response**

The review team agrees with the comment to remove the word “formalized” from the first paragraph in 3.1.d. The paragraph has been changed to read:

The review team considered the impact of the issues identified under the indicators Technical Quality of Inspections and Technical Quality of Licensing Actions when recommending a finding for this indicator. The review team determined that the lack of documented training for qualification resulting from the Program’s current procedure not being equivalent to IMC 1248, a lack of knowledge of the current training procedure by the new staff, and a lack of understanding on the expectation of how to become fully qualified led to the issues seen in those two indicators. The performance issues observed under inspection and licensing led the review team to recommend a downgraded finding for this indicator.

#### **Alabama Comment 4**

##### **3.3 c. Evaluation**

This area is arranged in a way that does not seem to flow correctly, and appears to bury the aspects of our program that are assets and which likely contributed to us not having a worse finding.

We were told by the reviewer that the inspections he witnessed, while showing a need for additional training and experience, were adequate in regards to health and safety. This is not stated in the report.

This section also has statements that are either erroneous or misleading. For example, stating "The new inspectors were under the impression that medical sealed sources did not need to be leak tested." leads one to believe that our inspectors did not believe that any medical sealed sources, including brachytherapy sources, should be leak tested. That is not true. The misunderstanding was over calibration and reference sources only.

Please provide further background on the statement "...when asked about instrument calibrations, therapy spot checks, and certain quality assurance tests, the inspectors indicated that they inspect for completion and not for validity or accuracy of the data and/or what would be considered outside of accepted values." Did he actually say that he does not check for "validity or accuracy of the data and/or what would be considered outside of accepted values?" In my discussions with the inspector in question, he stated that he did not tell the reviewer anything about checking for validity or accuracy of the data. Is it possible that this statement is an inference by the reviewer? I have asked our inspectors what they consider as they review QA/QC, and they have stated that they verify that it is performed each day of use and that it falls within the acceptable parameters specified for the equipment.

I request that the text be clarified and rearranged. Alternative wording:

The review team found that the new inspectors brief management after they have performed an inspection. This briefing includes a discussion that covers the inspections, start to finish. **However,** the review team noted some performance issues with quality of the inspections and casework for the newer inspectors.

During one of the accompaniments, the inspector did not **appear to have** ~~present with~~ the appropriate knowledge of the Increased Controls (IC), specifically on how a licensee approves unescorted access to quantities of concern and how the process should be inspected. In addition, during on-site interviews with the two newest

inspectors, it became apparent the inspectors lack a full understanding of several key areas for materials they are already inspecting independently. One example included an **apparent** lack of understanding of what constituted a medical event with regards to an I-131 therapy. A second example included a misunderstanding with regards to leak testing requirements. The new inspectors were under the impression that medical **calibration and reference** sealed sources did not need to be leak tested. ~~In addition, when asked about instrument calibrations, therapy spot checks, and certain quality assurance tests, the inspectors indicated that they inspect for completion and not for validity or accuracy of the data and/or what would be considered outside of accepted values.~~ **In reviewing the overall technical quality of inspections,** ~~the~~ the review team determined the **above** issues ~~are~~ **can be** attributed to the State's qualification process.

Based on interviews with management and staff, and reviews of case work, the review team resolved its performance concerns observed during the accompaniments and determined that during the review period Alabama met the performance indicator objectives listed in Section 3.3.a.

### **NRC Response**

The review team disagrees with the comment that the statement regarding leak testing of sealed sources is erroneous or misleading. During the inspector accompaniment, the reviewer witnessed the inspector telling the licensee that they did not need to leak test any of their sealed sources. When questioned along similar lines during the IMPEP review, the other inspector indicated that licensees did not have to leak test epoxy or resin sealed sources. These observations and statements are part of the basis for the overall issue raised with the State regarding the lack of training and experience of the new inspectors that led to the finding and recommendation in Technical Staffing and Training. However, the wording in the report was clarified to indicate "calibration and reference sources" as noted in the comment.

With regard to the statement "...when asked about instrument calibrations, therapy spot checks, and certain quality assurance tests, the inspectors indicated that they inspect for completion and not for validity or accuracy of the data and/or what would be considered outside of accepted values." the reviewer was told by the inspector that he looks for completion and not for specific numbers. Therefore, the NRC agrees that there was an inference by the reviewer as noted in the comment, but it was based on statements made by the inspector. The report was changed to indicate they inspect for completion, but the remaining part of the statement regarding validity and accuracy was removed. Again, these statements are part of the basis for the overall issue raised with the State regarding the lack of training and experience of the new inspectors that led to the finding and recommendation in Technical Staffing and Training.

The review team disagrees with rearranging the text under the evaluation section of Technical Quality of Inspections. The IMPEP teams are following an IMPEP report template for the presentation of findings.

### **Alabama Comment 5**

#### **3.4 b. Discussion**

In the second paragraph, the sentence “Specifically, one of the licenses was authorized for a high dose-rate remote afterloader (HDR) without an authorized user; another license was authorized to use palladium-103 and yttrium-90 without an authorized user.” While we believe we know the licensee with the HDR, we are unsure of whom you are referring to with the Pd-103 and Y-90 sources. Please provide more information.

In the third paragraph, the sentence “Additionally, the review team identified that financial assurance was not requested from pharmaceutical licensees in accordance with Alabama regulation 420-3-26-.02(26) “Financial Assurance and Recordkeeping for Decommissioning.”” Two of our three pharmacy/cyclotron licensees/registrants have submitted DFPs and one wanted us to give them an exception through license condition, which we denied. In these instances, it appears that the lack of a specific listing for cobalt 57 in Appendix A to 10 CFR Part 30 forces this issue. We encourage the NRC to address this problem by amending Appendix A of Part 30 to add a line item for cobalt 57.

In the fifth paragraph, the sentence “The review team identified that two authorized nuclear pharmacists did not have complete training documentation, in accordance with 420-3-26-.07(28) “Training for an Authorized Nuclear Pharmacist.”” Please provide us with the names of the pharmacists. We believe we know who one of them is. For this individual, we based our approval on an accepted method: that he was already listed on a license. We were able to determine that fact from our database. That individual had submitted required T&E documentation and was approved as an ANP on an Alabama license August 27, 2001. He remained on that license until October 15, 2009. During that period, he was approved and listed on another Alabama license based on already being an ANP on the first license. He later was listed on yet another Alabama license, again based on his continuous approval as an ANP on an Alabama license. The original T&E documentation was retrieved from the original file, which had to be retrieved from archives, and we did make copies of the original T&E and placed them into the other license files. However, that was not required to approve him as an ANP on the two licenses in question.

In the sixth paragraph, the sentence “The review team also identified several license folders that contained IC materials that were found in the regular file cabinets and did not contain any security related markings.” “Several” implies more than two. Please provide us with a list of IC licensees that were improperly filed. Further, we are not aware of any

files that contained IC materials and were kept in unlocked file cabinets. The two files that I believe are being referenced have no IC information such as security systems and procedures, background checks, T&R officers, etc. in the files. This is because they have not possessed radioactive material quantities of concern under their Alabama license. A condition of their licenses requires that they have all the IC order requirements in place before receiving RAM quantities of concern, which would include that they must provide us with the appropriate documentation. The two licensees that were pointed out to us do have authorization to possess quantities of concern, but are out of state licensees that have no permanent location or facility here in Alabama. They have not brought quantities of concern into Alabama (according to their required notification records) and, therefore, are not subject to the ICs.

### **NRC Response**

Regarding the comment on the second paragraph, the NRC will provide the detailed information separately to the State as requested.

Regarding the comment on the third paragraph, the NRC acknowledges that cobalt-57 is not listed in Schedule B of Part 30. For unlisted radionuclides, licenses and regulators should apply the default value for “any byproduct material not listed other than alpha and beta emitting byproduct material.”

Regarding the comment on the fifth paragraph, the NRC will provide the detailed information separately to the State as requested. At the time of the review, this matter was discussed with the State and it was agreed that the documented T&E on file for these individuals was not adequate to approve them as ANPs although they appeared qualified and did not pose a health and safety concern.

The NRC agrees with the comment on the sixth paragraph. Questions regarding ICs were brought up during the review and two particular files were discussed. From those discussions the reviewer was satisfied with the State’s actions; therefore, the statement in the report was removed.

### **Alabama Comment 6**

#### **3.4 c. Evaluation**

Again, the use of the term “formalized” seems subjective in that we had in place a training program that was found adequate and compatible during the 2010 IMPEP, but that did not meet the requirements of the current IMC 1248.

Alternative wording:

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The review team interviewed the licensing staff and although the primary reviewer was an experienced inspector, the training of the individual as a license reviewer ~~was not a formalized~~ **did not meet the** qualification process **of IMC 1248**, as discussed **earlier**. The review team attributed the licensing ~~errors~~ **issues** noted above to the lack of **incomplete** training and experience. Alabama is in the process of correcting the licensing ~~errors~~ **issues**. Despite ~~some~~ licensing **these** issues, the review team determined that during the review period Alabama met the performance indicator objectives listed in Section 3.4.a.

**NRC Response**

The NRC agrees with the comment and changed the wording in the report to that suggested by the State.