

file

May 1, 1998

MEMORANDUM TO: Richard L. Bangart, Director
Office of State Programs

FROM: /s/ R. J. Caniano (for)
Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

SUBJECT: PROPOSED AGREEMENT WITH THE STATE OF OHIO

In response to your February 27, 1998 memorandum to A. Bill Beach, Regional Administrator, Region III reviewed the January 23, 1998 Ohio draft application for Agreement State status. Our review was performed in conjunction with the review done by the Office of Nuclear Materials Safety and Safeguards. Attached to this memorandum are the comments we have regarding the application. While there are numerous comments, many are typographical and grammatical in nature.

In our bi-weekly calls with Ohio, we continue to provide feedback to the State regarding our review of their application.

Attachment: As stated

cc w/att: C. J. Paperiello, NMSS
P. F. Goldberg, NMSS
K. D. Cyr, OGC
T. T. Martin, AEOD
D. M. Sollenberger, OSP
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* See previous concurrence

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Division of Nuclear Materials Safety

SUBJECT PROPOSED AGREEMENT WITH THE STATE OF OHIO

In response to your February 27, 1998, memorandum to A. Bill Beach, Regional Administrator, Region III reviewed the January 23, 1998, Ohio draft application for Agreement State status. Our review was performed in conjunction with the review done by NMSS. As is obvious from the voluminous number of comments (attached), we identified a significant number of shortcomings in the proposed Ohio program; however, none appear to be critical failures.

In our bi-weekly calls with Ohio, we continue to provide feedback to the State regarding our review of their application.

Attachment: As stated

cc w/att: C. J. Paperiello, NMSS
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REGION III COMMENTS

OHIO APPLICATION FOR AGREEMENT STATE STATUS JANUARY 23, 1998 DRAFT

VOLUME I PROGRAM NARRATIVE

Table of Contents

The table of contents does not match the text. Two section Bs in table.

Page 1, line 5

Replace "to could not constitute and" with "not sufficient to form a"

line 11

Replace "are" with "is"

Page 2, paragraphs 2 and 3

Ohio already has authority for naturally occurring and accelerator-produced radioactive materials. These references should be removed.

Page 12, Section E.I., line 1

Replace "five three" with "has five"

Page 14, Section E

The staffing for the radiological laboratory is not discussed.

Page 16, lines 9-14

This paragraph indicates that close-out surveys will be performed at licensee facilities requesting termination of their licenses, to assure that no residual contamination has been left on site. This should be amended to indicate that no residual contamination will be left exceeding unrestricted release limits, and it should specify or reference what their unrestricted release limits are.

Page 23, line 2

Replace "NAVLAP" with "NVLAP"

Page 25, line 14

Replace "recycles" with "recycling"

Page 28, line 13

Mike Snee is listed as an HP3. The organization chart has him at HP2.

lines 20-21

Replace "(2) HP3-vacant" with "(3) HP3-vacant"

lines 23-24

Debbie Traylor is listed as Secretary. The organization chart lists Kristy Harbor.

last line

Does "HP3-Low-Level Radioactive Waste-vacant" refer to the "HP2 Party State" vacancy on the organization chart?

Page 31

Consideration should be made regarding the use of revised and updated Regulatory Guidance. The application makes reference to many old NRC guides. It is recommended that the State of Ohio adopt the consolidated Guidance currently being generated by NRC (i.e., NUREG-1556, Vol. 1 - Portable Gauge Licenses; Vol. 2 - Radiography Licenses; Vol. 3 - Sealed Source and Device Evaluations; Vol. 4 - Fixed Gauge Licenses; Vol. 5 - Self-Shielded Irradiator Licenses; Vol. 6 - Part 36 Irradiator Licenses, etc.)

In addition, the application contains a statement regarding the use of NRC regulatory guides that reads: "The State of Ohio has developed guides that follow the format and content of the NRC guides for these applications. However, as reference, the NRC guides are listed." It would appear to be appropriate that the guides developed by the State should be reviewed in detail to ensure that they are adequate and consistent with the NRC Regulatory Guides.

Page 37

"Instruction to Employees . . . will be complete no later than 9 January 1998."
Paragraph should be updated.

Page 38, line 9

Add the word "or" between "Pentium" and "486"

Page 40, third line from bottom

The statement "Current NRC guidelines call for 1.0 to 1.5 FTEs for each 100 licenses" is not true. NRC does not currently have specific guidance regarding staffing levels, but rather uses a performance view.

VOLUME 2

EXHIBITS

Page 48, draft agreement

Agreement numbering system is inconsistent.

Page 49, draft agreement

Category IX treats contaminated sites as a separate category. This should be deleted.

EXHIBIT 5

PROGRAM FOR THE LICENSING OF RADIOACTIVE MATERIALS

Page 8, second paragraph

Proposal to abandon any renewal application if a response to a deficiency letter is not received within 60 days, and requires reapplication for renewal. Not clear if original license remains in effect or if they are without a license.

Page 11

The Ohio License Category Number is 22200 for both "Pacemaker-Byproduct/Special Nuclear Material-Material-Manufacturing and Distribution" and "Decommissioning of Special Nuclear Material Facilities - <critical mass." It appears that the first program code should be 22162 and the second should be 22200.

Page 12, line 2

“General Licenses may be issued to any person who meets the criteria for a General License” It appears that issuance is automatic if the person meets the criteria. Therefore, it appears that the words “may be” should be replaced by “is.”

Page 14, sixth bullet

The procedure requests that the applicant provide the page number where the sealed source or device is listed in the NRC sealed sources and device registry (SSDR). It should request the SSDR registry number, not the page number.

Page 16, fourth bullet

Authorizes up to 750 mCi of hydrogen-3 in automobile shift quadrants where as 10 CFR 30.15(a)(4) limits this to 25 mCi.

fifth bullet

Doesn't specifically address marine compasses containing up to 750 mCi hydrogen-3, as addressed in 10 CFR 30.15(a)(5).

fourteenth bullet

“. . . instruments that do not contain” It appears that “do not” should be deleted.

fifteenth bullet

The activity limit specified for spark gap irradiators, 10 microcuries of cobalt-60, is non-conservative compared with corresponding NRC criteria of 1 microcurie of cobalt-60 in 10 CFR 30.15(a)(10).

Page 17, second paragraph

Requires certain disposal requirements and obligations on exempt items. The NRC has no such disposal restrictions on these items.

Page 27, fourth bullet

Appears something is missing after the word “radioactivity.” Possibly the word “remains” should be inserted.

Page 28, second bullet

Replace “that” with “than”

fourth bullet

Replace “that” with “than”

Appendix A, page 6

It appears that promethium-147 should be 2E-3 rather than 4E-4 and Pm-149 should be 4E-4 rather than 1E-6. Reference: 10 CFR 30.70, Schedule A-exempt concentrations.

Missing exempt concentration values for Protactinium (91).

Appendix A, page 8

It appears that Sr-92 should be 7E-4 rather than 1E-6. Reference: 10 CFR 30.70, Schedule A- exempt concentrations.

Appendix C, page 1

The Quantity in Curies for cadmium-113 should be 80 rather than 1000. Likewise, the Quantity in Curies for calcium-45 should be 20,000 rather than 80. Reference: 10 CFR 30.72, Schedule C.

Appendix C, page 2

Iodine-131 values are not listed. The Release Fraction should be 0.5 and the Quantity in Curies should be 10. Reference: 10 CFR 30.72, Schedule C.

Appendix C, page 5

Incorrect footnote number for Packaged Waste, alpha. The correct footnote number is 1. Reference: 10 CFR 30.72, Schedule C.

Appendix D, page 1

"Required Amounts of Financial Assurance for Decommissioning by Quantity of Material," for sealed sources or plated foils should be corrected as follows:

In Sealed Sources or Plated Foils - if the quantity is greater than 1E10 the applicable quantities of Schedule 1 (for a combination of isotopes, if R, as defined below, divided by 1E10 is greater than unity). Reference: 10 CFR 30.35(d).

Appendix D, page 2

Cesium-134 and its amount of 1 microcurie was left off the schedule. Reference: Appendix B to 10 CFR 30.

Cesium-135 is incorrectly listed as 1 microcurie; the correct value is 10 microcuries. Reference: Appendix B to 10 CFR 30.

Appendix D, page 5

Need to add potassium-42, 10 microcuries to the schedule. Reference: Appendix B to 10 CFR 30.

Need to add scandium-46, 10 microcuries to the schedule. Reference: Appendix B to 10 CFR 30.

Appendix D, page 7

Yttrium-192 should be yttrium-92. Reference: Appendix B to 10 CFR 30.

Appendix E, page 2

Ba-131, Column II should be 0.1 rather than 0.01. Reference: 10 CFR 33.100, Schedule A.

Appendix E, page 4

I-129, Column II should be .01 rather than .001. Reference: 10 CFR 33.100, Schedule A.

Appendix E, page 6

Os-191, Column I should be 10.0 rather than 100.0 and Column II should be 0.1 rather than 1.0. Reference: 10 CFR 33.100, Schedule A.

Appendix E, page 7

Pr-142, Column I should be 10.0 rather than 0.1 and Column II should be 0.1 rather than 0.001. Reference: 10 CFR 33.100, Schedule A.

Re-186, Column I should be 10.0 rather than 100.0 and Column II should be 0.1 rather than 1.0. Reference: 10 CFR 33.100, Schedule A.

Appendix E, page 8

Ru-106, Column II should be 0.001 rather than 0.0001. Reference: 10 CFR 33.100, Schedule A.

Need to add Sr-85m, Column I amount 1,000.0 and Column II amount 10.0. Reference: 10 CFR 33.100, Schedule A.

Appendix E, page 9

Te-132, Column I should be 1.0 rather than 10.0 and Column II should be 0.01 rather than 0.1. Reference: 10 CFR 33.100, Schedule A.

General licensing program recommendations:

Establish a program for the security of decommissioning financial assurance instruments. In addition, establish a process for the delegation of signature authority for drawing on decommissioning financial assurance instruments. The program used by NRC to ensure the security of financial assurance instruments is Management Directive 8.12, "Decommissioning Financial Assurance Instrument Security Program."

Establish a Quality Assurance (QA) assessment program to improve the overall effectiveness and ensure a uniform review of licensing casework. Region III uses a team approach to QA reviews of licensing casework. The teams are usually lead by a senior reviewer and a certain percentage of files are reviewed monthly. A checklist is utilized to document the QA reviews. The results of the QA reviews are maintained and recorded in a memorandum to the Branch Chief.

Establish a procedure for addressing coordinated Agency actions to deal with licensees that declare bankruptcy. A recommended guide to use is Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy."

Establish a procedure on handling license applications involving change of ownership. The procedure should include a process that incorporates information concerning the transferee's liability for open inspection and enforcement issues, decontamination activities, and decommissioning of the sites. The recommended guidance to use is NRC Information Notice 89-25, Rev. 1: "Unauthorized Transfer of Ownership or Control of Licensed Activities."

EXHIBIT 6

INSPECTION PROGRAM FOR RADIOACTIVE MATERIALS

Page 2, line 14

Replace "As Low As is reasonably Achievable Program (ALARA)" with "As Low As Reasonably Achievable (ALARA) program."

Page 3, Field Inspection definition

Replace "irradiator's" with "radiographer's"

Page 3, Follow-up Inspection definition

This sentence would imply that an inspection is an enforcement action and would indicate that only “escalated” cases have a follow-up inspection. Follow-up inspections may be performed for a variety of reasons.

Page 12, second paragraph

Inspection priorities should not be changed based upon inspection results. The frequency of future inspections may be changed.

Page 12, Initial Inspection paragraph

Initial inspection procedure, requiring an inspection within six months of license issuance, is more stringent than NRC IMC 2800 requirement to perform inspections within six months of receipt of material, or within one year of license issuance if no material is possessed.

Page 13, Reciprocity Inspections paragraph

Text should be added to this paragraph to recognize that reciprocity is not needed for NRC licensees working in areas of Exclusive Federal Jurisdiction. Also, handling of reciprocity requests should be addressed. See NRC IMC 1220.

Page 13, Scheduling Inspections, second bullet

Inspection priorities should not be changed based upon inspection results. The frequency of future inspections may be changed.

Page 16, third paragraph

Replace “Appendix B” with “Appendix A”

Page 18, line 10

Replace “licensing” with “inspection”

Page 25, Inspection Report example

Summary of Findings and Actions has “non-conformances,” “violations,” and “deficiencies.” Procedures refer to “non-compliances.” Use of these terms is confusing.

EXHIBIT 7

GENERAL ENFORCEMENT POLICY

Page 13

The second paragraph is partially duplicated on page 14 at the first paragraph. This duplication is confusing and should be resolved.

The second paragraph states that administrative penalties will normally be assessed for Severity Level I, II, III, and IV violations. A similar statement is contained in the first paragraph on page 14 except that it only references Severity Level I and II violations. These statements contradict each other.

The fourth paragraph is duplicated on page 14 at the second paragraph.

Page 14, Table 1

The dollar amounts may be based solely on the Severity Level and apparently do not consider the ability of the licensee to pay. The NRC enforcement policy has a civil penalty scale that acknowledges the licensee ability to pay. The sliding scale ensures

that the civil penalty is based on the type of license and the type of licensed activity. The State of Ohio may want to revisit this issue to ensure that the administrative penalty considers the type of license, the type of licensed activity and the licensee's ability to pay.

Page 17

The four decision points for the administrative penalty assessment process consider whether the license should be given credit for action related to "identification" and if the licensee's corrective actions were "prompt and comprehensive." Consideration should be given to include a definition section to define these terms and include verbiage in the enforcement policy describing how the terms are used.

Attachment A, Examples of Violations-Listed by Severity Level

Differences in Ohio and NRC violation severity levels were noted. Examples include:

Items 5 & 6 of the example for a Severity Level II violation (release and disposal of radioactive material) are the same as the NRC examples item 5 & 6 for Severity Level I violations.

Item 5 of the example for a Severity Level I violation (ALARA) is the same as the NRC example 4 for a Severity Level IV violation.

Item 7 of the example for a Severity Level I violation (failure to report) is the same as the NRC example 7 for a Severity Level II violation.

EXHIBIT 8 INCIDENT RESPONSE PROGRAM

Page 5, third paragraph of Subsection 2.2.1

Includes an unclear reference to an "Activation Mode," which was a term that was neither defined as one of the Bureau's "Response Roles" in Subsections 2.2.2 through 2.2.6 nor as one of the "Response Modes" defined in Subsection 2.4.

Page 7-8, Subsection 2.2.6

It is unclear why this investigatory role is apparently limited to dealing with allegations rather than also including a root cause investigation function following an event that warranted an incident response.

Page 9, first paragraph of Subsection 2.5

Contains a statement that is inconsistent with the Response Modes defined in Subsection 2.4. Specifically, Subsection 2.5 incorrectly indicates that Initial Activation and Expanded Activation would "nearly always be (the) two modes of activation." Subsection 2.4 also defines a Standby Mode during which the Bureau's response would be directed from its Incident Response Center (IRC) prior to the possible deployment of a "Site Response Team." Subsection 2.2.2 describes a "Monitoring-Only Role" in which the Bureau's response would be "essentially passive and confined to information acquisition and assessment." Thus, it appears that the Bureau could remain in the Standby Mode during which the IRC's "Standby Team" led by an Emergency Director would accomplish the Bureau's "Monitoring-Only Role."

The Incident Response Program lacked adequately detailed information on the following:

- a. What provisions would be in place to better ensure that adequate numbers of the Bureau's key response personnel would be available to report for duty within a reasonable time period (e.g., about 60 minutes) during non-business hours. There was no clear indication that key response personnel would be equipped with pagers or other devices to better ensure that they could be readily contacted during non-business hours. There was no clear indication that some type of "call out list" for the Bureau's responders would be periodically verified to better ensure that responders' listed home telephone numbers remained correct.
- b. It was unclear whether sufficient Bureau personnel would be qualified to serve as Director of Site Operations (DSO), since Subsection 2.6 indicated that the DSO was "usually" a supervisor and since Bureau supervisors would also be members of the IRC's Executive Team.
- c. Although the Bureau's Executive Team and the hierarchy of persons who would become Emergency Director were adequately described, it was unclear how many Executive Team members must be available in order for the Executive Team to perform required functions.
- d. No information was provided on the numbers of Bureau response personnel who would fill response positions that were not part of the Executive Team. No assessments could be made of the adequacy of the total numbers of Health Physics and other personnel who would fill needed positions in the IRC's "Standby Team" and "Site Response Team," or whether the Bureau would have sufficient numbers of qualified personnel to simultaneously respond to two emergency events.

Page 11, Subsection 2.7, item (16)

Does not adequately summarize the protective action recommendation decision making guidance to be used by the Bureau's key responders.

A "severe incident" is described as having "immediate dire consequences" to the public. The term "immediate dire consequences" should be quantified with respect to either the relevant Protective Action Guides, or to exposure limits in 10 CFR Part 20, or relevant limits in the State's laws, so that the Bureau's responders need not waste time during an emergency trying to decide what level of exposure may constitute "immediate dire consequences."

Page 15, Subsection 3.7

Should indicate a commitment that the telephone notification means to be used by licensees to report events to be Bureau is staffed by a duty officer or another reliable party at all times, so that the Bureau can respond in a timely manner to events that may warrant activation of its Incident Response Program during business and non-business hours.

Procedure NMS-IR-001

Should include NRC's Response Coordination Manual-96 (RCM-96) (NUREG/BR-0230) as another reference document used by NRC's incident responders.

Procedures NMS-IR-002 and NMS-IR-003

Includes unclear references to a "NRC/FEMA Incident Response Plan" that should be clarified. It is unclear whether the "NRC/FEMA Incident Response Plan" was intended to refer to one of the following: NUREG-0654/FEMA REP-1 (dated 1980), which is a document providing guidance on the content of licensee, State, and county emergency plans for power reactor sites; NUREG-0981/FEMA-51 (dated 1983), which summarized NRC's and FEMA's operational responses to a commercial power reactor accident; the Federal Radiological Emergency Response Plan.

Procedure NMS-IR-002

Incorrectly refers to Management Directive (MD) 8.2 as being NRC's Incident Response Plan. MD 8.2 is entitled "NRC Incident Response Program" and did not replace NRC's Incident Response Plan (NUREG-0728, Revision 2).

Procedure NMS-IR-002, Section 3.A.3

Lacks specific guidance on what "large dose" of radiation would warrant contacting a medical consultant.

Procedure NMS-IR-002, Section 3.A.4

In addition to contacting the NRC Headquarters Operations Center for chemical safety support, the procedure should also indicate that the National Response Center can also be contacted in order to obtain support from the U.S. Environmental Protection Agency (EPA) per the National Contingency Plan.

Procedure NMS-IR-002, Section 3.C.1

Indicates that "immediate" dispatch of one or more inspectors to the scene of an incident means "typically within 24 hours," which does not seem to be a timely on-scene response within a State.

Procedure NMS-IR-002, Section 4, first line

Replace "should" with "shall"

Procedure NMS-IR-002, Section 4.A.1

Should be revised to indicate that the Bureau need only notify the NRC Headquarters Operations Center and not also the Region III Office of such an event report. The Headquarters Operations Center has dedicated Operations Officers intended to be NRC's focal point for incoming event reports. (During non-business hours, calls to the Region III Office are automatically diverted to the Headquarters Operations Center.)

Procedure NMS-IR-002, page 11

Incorrectly indicates that the State needs to request DOE's Aerial Measurement System (AMS) support through the NRC Headquarters Operations Center. AMS is a DOE asset. Per Section J of RCM-96, DOE Headquarters must approve the deployment of the AMS following a request received from a State made to DOE Headquarters or the relevant DOE Regional Office. It would be reasonable for the Bureau to advise the NRC Headquarters Operations Center that DOE was requested to provide AMS support.

Procedure NMS-IR-002, Appendix A

Should be revised to commit that the answering service used to forward event reports to the Bureau's management would do so in an expeditious manner. Appendix A did not clearly indicate whether the Bureau would keep its answering service advised on the availability of the prioritized list of managers and supervisors, so that the answering service would not waste time trying to contact someone who would be unavailable to make a response mode decision. Appendix A should indicate that the answering service could not successfully complete its notification responsibility by leaving a voice message on a Bureau manager's or supervisor's telephone answering device.

Procedure NMS-IR-002, Appendix B

Lists an incorrect telephone number for the NRC Region III Office. The 24-hour telephone number for the National Response Center should be added. The 24-hour telephone number of the DOE Headquarters' Emergency Operations Center and the 24-hour emergency number to obtain DOE Region V's Regional Assistance Program (RAP) support should be added. The daytime and off-hours telephone numbers for DOE's Radiation Emergency Assistance Center/Training Site (REAC/TS) should also be added.

Procedure NMS-IR-003, Page 4

DOE's REAC/TS asset should be listed as a Federal source of medical advice.

Procedure NMS-IR-003, Attachment A, Page 3

Contains a "NOTE" whose conservatism and technical basis seem questionable. Though the Bureau defines "potentially exposed" members of the public as those who may have received a dose in excess of 100 mrem, "Group B" includes only those who may have received an estimated 500 mrem to 5,000 mrem, thus apparently dropping from the Bureau's further concern any non-pregnant members of the public who may have received an unplanned, non-occupational exposure between 100 and 499 mrem. The Bureau apparently considers the 500 mrem limit to be acceptable for a "transient situation, such as in accident scenarios." However, an accident scenario would involve an unplanned, non-occupational exposure in an uncertain situation to members of the public, who happened to be in the wrong place at the wrong time.

Procedure NMS-IR-003, Attachment A, Page 3

Contains non-conservative guidance on the State's efforts to identify members of the public who may have had an unplanned exposure up to 5,000 mrem. The attachment indicated that the Bureau or other State agencies need not spend "significant time or resources" trying to locate members of the public who may have received unplanned exposures up to 5,000 mrem. However, the attachment also indicated that the more stringent dose limit (500 mrem) was recommended for "women who think they may be pregnant." Thus, it seems more prudent for the State to spend reasonable time and resources to locate all members of the public who may have received an unplanned exposure of 500 mrem in case such persons could include "women who think they may be pregnant."

Procedure NMS-IR-003, Attachment A, Page 4

Includes non-conservative guidance that members of the public who may have received a calculated, unplanned exposure between 5,000 and 10,000 mrem

Page 7

This procedure does not appear to identify the approval authority for formal certification after completion of training requirements.

Page 12

Ohio may wish to consider an "Interim Qualification" program which certifies inspectors to perform only certain types of inspections (i.e., nuclear gauges and devices).

Page 13, fourth paragraph

It is not clear who has approval authority for exemptions or how will they be documented.

Appendix A, page 5

Oral Examination Board results should be documented.

Appendix A, Training Matrix

The training matrix should have a supervisory sign-off.

Appendix F - NRC Required Courses -- Noted below is the actual MC 1246 title and course #'s.

<u>Course Title Listed in Application</u>	<u>Actual NRC MC 1246 Course Title & #</u>
Applied Health Physics	Applied Health Physics (H-109)
Radiation Protection Engineering	Site Access (H-101) or NMSS Radiation Worker Training (H-102)
Medical Uses of Radionuclides	Diagnostic and Therapeutic Nuclear Medicine (H-304)
Transportation	Transportation of Radioactive Materials (H-308)
Industrial Radiography	Safety Aspects of Industrial Radiography (H-305)
Materials Licensing	Licensing Practices and Procedures (G-109)
Inspection Procedures	Inspection Procedures (G-108)
Teletherapy & Brachytherapy	Teletherapy & Brachytherapy (H-313)
Irradiator Technology	Irradiator Technology (H-315)
Air Sampling for Radioactive Materials	Air Sampling for Radioactive Materials (H-119)
Environmental Sampling & Analysis	Environmental Monitoring for Radioactivity (H-111)
Health Physics Technology	Health Physics Technology (H-201)
Inspecting for Performance	Inspecting for Performance-Materials Version (G-304)
Health Physics Topical Review	Health Physics Topical Review (H-401)
Well Logging	Safety Aspects of Well Logging (H-314)
Special Topics Workshop	-----
Investigation Training	Root Cause/ Incident Investigation Workshop (G-205)
Regulations Workshop	-----
LLW Regulators Workshop	-----

The following NRC courses may be added to the list of training courses offered by NRC:

Radiological Surveys in Support of Decommissioning (H-120)
Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) (H-121)
Internal Dosimetry and Whole Body Counting (H-312)

EXHIBIT 12

QUALITY ASSURANCE PLAN FOR RADIOLOGICAL AND ENVIRONMENTAL SAMPLING EVOLUTIONS

Page 1, line 16

Statement is limited in scope. Should include analyses, record keeping, etc.

Page 5, line 1

Does this provide adequate independence in the management chain, or should this position report somewhere higher in the management chain?

Page 6, line 9

What is the range? What is an acceptable range?

Page 6, line 12

This paragraph should have a reference.

Page 6, line 19

This sentence should read "Accuracy is a measure of laboratory analytical capabilities."

Page 6, lines 31-33

The sentence beginning "The analysis will be" needs clarification.

Page 6, line 35

Replace "representativeness" with "sample integrity"

Page 7, lines 1-2

Sentence is unclear.

Page 7, line 14, Section 3.6

This paragraph is unclear and needs to be better explained.

Page 7, line 32

What is meant by "off-site laboratory"?

Page 8, lines 8-12

This paragraph should be deleted.

Page 9, lines 9-10

If this is minimal detectable activity (MDA), it should state it and define MDA or provide a reference.

Page 9, line 26, Section 3.8

It is not clear if the laboratory will be performing analytical chemistry as well as radiochemistry. This document contains many references to analytical methods that may not have anything to do with radiochemistry.

Page 12, line 2

Define abbreviations "AC, AT, EC, CR."

Page 12, line 25

Replace "NAVLAP" with "NVLAP"

Page 13, line 32

What is a field quality assurance sample? What would the data be used for?

Page 15, lines 21-22

Sentence meaning is not clear.

Pages 15-16, Sections 6.1-6.2

Need to address software validation, ISO 9000 certification and year 2000 problems.

Page 18, lines 20-21

Define "PAC"

Reference to "Section 15.0"?

Page 20, line 16

Who is the Sampling Officer?

Page 20, lines 32 and 36

Replace "data" with "date"

Page 22, line 10, Section 7.0

This section should be more explicit in addressing independent verification and cross check programs.

Page 23, line 21

The term "Technical Specification" could be deleted.

Page 23, lines 30 and 33

Is this sufficient time to perform a Root Cause Analysis and develop corrective actions?

Page 26, Sections 11.2-11.5

These are similar to Sections 10.1-10.4.

VOLUME 3

APPENDICES - ATTACHMENTS

APPENDIX 5

EQUIPMENT AND INSTRUMENTATION

Page 1

The type and quantity of analytical equipment available is not addressed, only field instrumentation is described.

ATTACHMENT E

PROGRAM ASSESSMENT REVIEW

Page 2

Non-common indicators are not addressed. See Management Directive 5.6.

Page 2, item 1, first bullet

Core license inspections should include initial inspections of new licenses.

Page 2, item 1, second bullet

Inspection priorities should not be changed based upon inspection results. The frequency of future inspections may be changed.

Page 5, item 3, second bullet

The response "What?" is not clear.

Page 7, item 4, sixth bullet

Annual supervisory accompaniments of inspectors should be performed.