

Mr. Roger L. Suppes, Chief  
 Bureau of Radiation Protection  
 Ohio Department of Health  
 35 East Chestnut Street  
 Columbus, OH 43266-0118

JUL 29 1998

*Ohio file*

Dear Mr. Suppes:

This letter is in further response to your January 23, 1998, letter forwarding the draft of a request by Ohio Governor Voinovich for an Agreement between the Nuclear Regulatory Commission and the State of Ohio. In our letter of June 18, 1998, we identified two major issues: (1) the definition of the term "decommissioning" in Ohio law, and a provision of Ohio law which prohibits disposal of certain radioactive wastes at an unlicensed site; and (2) the staffing of the Agreement materials program. We also indicated that Nuclear Regulatory Commission (NRC) staff has identified other items in the draft request for an Agreement which need modification or clarification to ensure that the Ohio program will be adequate and compatible, and that the specific staff comments or requests for further information will be provided to you under separate cover.

Accordingly, NRC staff has divided their remaining comments into two categories. The first list (Enclosure 1) contains comments which the Ohio program will need to address in the formal request for an Agreement signed by Governor Voinovich. The second list (Enclosure 2) contains comments which are suggestions for you to consider to improve the Ohio program. In addition, as discussed during our July 16, 1998 conference call, NRC staff plans to review a sampling of the program's procedures and guidance for licensing, inspection and enforcement. We will coordinate this review with you.

If you have any questions about the enclosed, please contact me at (301) 415-3340 or Mr. Richard Blanton of my staff at (301) 415-2322 or by E-mail at RLB@NRC.GOV.

Sincerely,

**Original Signed By**  
**RICHARD L. BANGART**  
 Richard L. Bangart, Director  
 Office of State Programs

Enclosures:  
 As stated

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

July 29, 1998

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Sincerely,

*Richard L. Bangart*  
Richard L. Bangart, Director  
Office of State Programs

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As stated

## **COMMENTS THAT MUST BE ADDRESSED IN THE FORMAL APPLICATION**

Comment related to waste disposal. (The comment below is in addition to the comments addressed in our separate letter on significant issues).

1. In Volume 2 of the application ("Exhibits"), Exhibit 5 ("Program for the Licensing of Radioactive Materials"), in the section entitled "Specific Exemptions," starting on page 15 is a list of materials and items described as exempt from "specific licenses." On page 17, the second paragraph indicates that the Ohio program will impose disposal requirements on exempt materials and items. It is not specified how the disposal requirements will be enforced. Under the Nuclear Regulatory Commission (NRC) program, the listed materials and items are exempted from all regulatory control, including disposal requirements, not just licensing, once they are transferred from an NRC licensed distributor holding a valid exempt distribution license to any other person (i.e., a member of the public). [Please note that the authority to license exempt distribution is reserved to the NRC and does not transfer to a State under an Agreement. See 10 CFR 150.15(a)(6)]. Further, there is no requirement on NRC exempt distribution licensees to report the transfer of radioactive materials to other persons. In order to avoid the creation of a regulatory conflict, it is recommended that the "Program for the Licensing of Radioactive Materials" be revised to exempt the listed materials and items from all further regulatory control, including disposal requirements.

Comments related to the Sealed Source and Device (SS&D) Program.

2. The "SS&D Review and Registration Program" indicates that a standard review plan (SRP) modeled on NUREG-1550 will be used. It is implied that the Ohio staff will use the template registration certificates and checklist from NUREG-1550 to assist in the review of SS&Ds and to help to ensure that all pertinent issues are addressed. The "SS&D Review and Registration Program" should indicate that the templates and checklist will be used as guidance by the reviewers.
3. In the SRP for SS&Ds, the definition of "inactive vendor" states that the term refers to "a vendor who no longer may be authorized to initially distribute the sealed source or device listed on a registration certificate but may provide services for the sealed source or device." The words "be authorized to" should be inserted between the word "may" and the words "provide services."
4. In the SS&D program description, it should be noted that NUREG-1550 will be replaced by NUREG-1556, Vol. 3, which is expected to be issued in final in the near future. Ohio should reference NUREG-1556, Vol. 3, when it is issued.
5. In the "SS&D Review and Registration Program," the following issues should be addressed: (a) foreign vendors; (b) custom certificates -- NRC policy is to limit the number of custom use certificates for any single design to two or three, then strongly encourage the distributor to commercially register the design; (c) identification of

ENCLOSURE 1

principle use code definitions - note that NRC's NUREG-1556, Vol. 3, is intended to replace both Regulatory Guides 10.10 and 10.11.

6. The SRP for SS&Ds, section for Distribution of Completed Certificates, should specify that a copy of the completed certificate is to be forwarded to the NRC for inclusion in the National Registry.
7. In the SRP for SS&Ds, the Document Flow section states that the "director" signs the certificate. The purpose and scope of this action should be clarified.
8. In the SRP for SS&Ds, introductory paragraph to the section "Rules in the OAC that Address Specific Registration Requirements," the wording is unclear in reference to the custom products reviews. It should be clarified that each Agreement State performs custom reviews only for those custom users located in that state, and similarly NRC performs custom reviews only for those custom users located in states under NRC jurisdiction.
9. In the SRP for SS&Ds, throughout the section "Rules in the OAC that Address Specific Registration Requirements," OAC regulations are referred to "as referenced to the equivalent NRC regulation." In some cases, it appears that the referenced NRC regulations are not applicable. For example, the section on radiography lists as references NRC's 10 CFR 31 (for general licenses) and 10 CFR 39 (for well logging), neither of which apply. The references should be reviewed and corrected as necessary.
10. In the SRP for SS&Ds, section "Devices used under General License," there appear to be inconsistencies when referring to Ohio chapters 3701-38 and 3701-39. 3701-38 is used to refer to both the part of the regulations under which persons may use devices with general license (pg. 13), and to the part of the regulations under which generally licensed device must be manufactured and distributed. The references should be reviewed and corrected as necessary.
11. In the SRP for SS&Ds section "Sealed Sources and Devices for Medical Use," it states that teletherapy sources do not need to meet the listed regulations. It should be noted however, that 10 CFR 35.49(b) requires that licensees use only sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30. Since Ohio adopted these regulations by reference, Ohio licensees will face the same requirements. The wording of this section of the SRP should be clarified.
12. In the SRP for SS&Ds sections for the specifically licensed products, the statement is made that the "manufacturer or distributor of the equipment may demonstrate that the equipment meets these requirements." It should be noted that a custom user may also submit the information in support of issuance of a custom use certificate.
13. In the SRP for SS&Ds section "Limitations and Other Considerations of Use" under the main section "Writing the Certificate," it states that there are limiting conditions such as leak testing, handling, storage, use, transfer, disposal, environmental conditions, labeling, special handling procedures and tools and specific licensing conditions that

"may be performed" by the license reviewer. This wording should be replaced with "should be addressed" by the license reviewer.

14. Under the "Limitations and/or Other Considerations of Use" section of the standard device certificate format in the SRP for SS&Ds, the standard wording in some of the limitations states "the device shall be distributed to persons specifically licensed by the state of Ohio, the US NRC, any state with NARM regulations, or another agreement state." A note should be added that for products containing byproduct material, the reference to "any state with NARM regulations" is not appropriate.
15. In the "Accompanying Documentation" section of the checklist in Appendix A to the SRP for SS&Ds, it states that the reviewer must "verify information forwarded to NRC for update of NRC source listing." It appears that the correct reference should be to NRC's generally licensed device listing. Also, for general license distribution, the checklist should include an item to confirm that copies of pertinent regulations will be provided with the device.
16. Throughout the SRP for SS&Ds, there are a number of examples where references to guidance for exempt use product reviews and the specific requirements imposed on the product design that need to be addressed during the product evaluation are cited. The wording in the SRP should be clarified to indicate that Ohio is not authorized to perform evaluations of exempt use products containing byproduct material. (See, for example, Appendix A - first page information, Appendix A - smoke detector reference in Description/Construction, Appendix A - dose limit for exempt distribution in Conditions of Use, Appendix B - reference to NUREG/CR-1156, Appendix C - reference to smoke detector standards. Appendix D - standard format for a smoke detector/gun sight)
17. The SRP for SS&Ds, section regarding the assignment of certificate numbers, indicates that the Bureau will assign vendor numbers. As manager of the National Registry, NRC issues the new vendor numbers, for both active and inactive vendors. The guidance should be corrected to indicate this, and should further explain that the unit number is assigned by the Bureau after consulting the National Registry to determine the next available number.
18. The "SS&D Review and Registration Program" should contain a clear description of what constitutes a concurrence review, and describe Bureau policy/procedure on this issue. The description should be consistent with the following evaluation criteria from NRC Management Directive (M.D.) 5.6, dated November 25, 1997 (Handbook 5.6, Part III, Non-Common Performance Indicator 2)

"An independent technical review of the application and proposed certificate of registration is performed by a second individual and supports the finding that the product is acceptable for licensing purposes. (It is important to keep in mind that the independent technical reviewer must concur with the initial review.)"

(Footnote 2) "A concurrence review includes an independent technical review of the materials submitted by the applicant and the documents generated by the

initial reviewer. The concurrence review includes evaluation of each area addressed during the initial review (e.g., construction of the product, labeling, and prototype testing), but the concurrence review is not to the same level of detail as the initial review (i.e., it is not necessary to review every page of the applicant's submittal). The concurrence review must be focused on ensuring that the product meets all applicable regulations, that the product would not pose any health or safety concerns, and that the registration certification provides an adequate basis for licensing. This concurrence review by a second qualified reviewer is necessary in view of the potential health and safety implication resulting from the widespread distribution of sealed sources and devices."

The purpose of these guidelines is to ensure that each area of the review is addressed by two qualified individuals. As an alternative, one of these individual reviewers may be replaced by a team, where two or more individual reviewers combine to perform a complete review. The team must cover all areas of the review, and the team review must be independent of the individual reviewer. The designated leader for the team should sign the registration certificate.

If limited signature authority and/or the team approach will be used, then the State should clearly describe how the program will work, including how it will assign review areas to each reviewer in order to ensure that all areas are adequately covered, how team member responsibility will be documented (since the team leader signs the certificate for the entire team), and what the role and responsibilities of the team leader will be.

If the technical reviewers do not sign the certificate themselves, but rather certify the results of the technical review to the Director or another person designated by law to sign official documents, this procedure should also be described.

19. The "SS&D Review and Registration Program" should contain information regarding the number and training of individuals that will be considered qualified to independently perform SS&D reviews. The "SS&D Review and Registration Program" should describe the minimum qualifications, name the current staff members that will be initially assigned to SS&D evaluations, and indicate the estimated amount of time each assigned individual will spend performing SS&D evaluations and related duties.

It is noted that the "SS&D Review and Registration Program" on page 7 refers to a specialized segment of the training program for staff conducting SS&D reviews. This segment was not found in the "Training Program for Health Physics Personnel," Exhibit 10 of Volume 2. The segment should be included in the training program, or if the segment is located elsewhere, the location should be identified in the SS&D Program.

20. The "SS&D Review and Registration Program" should describe how the State determines individuals to be qualified to independently perform SS&D reviews. Independent review authority should be given only to those reviewers that are qualified to perform all areas of the evaluation. Limited review authority to perform specific areas of the evaluation could be granted to reviewers not having qualifications in all areas.

The procedure for determining individuals to be qualified to independently perform SS&D reviews should be consistent with the following criteria from NRC M.D. 5.6, dated November 25, 1997 (Handbook 5.6, Part III, Non-Common Performance Indicator 2):

".... Newly hired employees need to be technically qualified. Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences. Both initial and concurrence reviewers should be able to:

- Understand and interpret, if necessary, appropriate prototype tests that ensure the integrity of the products under normal, and likely accidental conditions of use,
- Understand and interpret test results,
- Read and understand blueprints and drawings,
- Understand how the device works and how safety features operate,
- Understand and apply appropriate regulations,
- Understand the conditions of use,
- Understand external dose rates, source activities, and nuclide chemical form, and
- Understand and utilize basic knowledge of engineering materials and their properties."

The importance of a qualification procedure in the SS&D program must be stressed. The procedure provides assurance that before a reviewer is given independent review authority, he or she is first evaluated to ensure she or he meets the established minimum standards, through experience, training, and/or formal education, to be able to fully address all issues in the areas for which he or she is being granted independent review authority. The qualification procedure also provides assurance that reviewers complete a sufficient number of cases, which are critiqued by a qualified SS&D reviewer to determine whether the reviewer seeking qualification adequately identified and addressed all pertinent issues. Independent review authority must be granted prior to the reviewer signing any registration certificates, or certifying registration certificates for the signature of a person designated by law to sign official documents. In order to obtain experience in SS&D reviews, staff could be assigned cases to work on, with all deficiency letters being reviewed by a staff member with independent review authority before issuance. When the reviewer-in-training concludes that she or he has identified and addressed all issues, the certificate must be reviewed IN FULL, by two staff members with independent review authority, or by one staff with independent review authority, and a team. The staff that works with the reviewer-in-training can be one of the independent reviewers. It is recommended that an independent review authority qualification procedure be established for all SS&D reviewers, including those that will be the start-up staff for the SS&D byproduct evaluation program.

21. The "SS&D Review and Registration Program" indicates that if an area of an SS&D review is identified where the Bureau staff does not have sufficient qualification, a process is in place whereby the assistance of qualified individuals can be obtained, and the review area (or action) in question would be assigned to those individuals. If this process will be used, the "SS&D Review and Registration Program" should clearly

explain the process, including how the process will ensure that the assigned individuals are qualified, and whether or not they will be evaluated and granted signature authority. If not granted signature authority, the explanation should include a description of how the signature for the registration certificate will be handled.

22. The "SS&D Review and Registration Program" indicates that Ohio will review incidents involving SS&D products evaluated and registered by the State to determine whether the incident indicates a product fault, and that the State will take appropriate action. However, Ohio should commit to a policy whereby, if an incident involves a product evaluated and registered by another Agreement State, or the NRC, then information regarding the incident will be forwarded to that regulatory agency, so that they can determine whether the incident indicates a product fault, and take appropriate action.
23. A copy of each of the following procedures should be included with the Governor's request:
  - Rule Implementing Guide, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Source and Devices Containing Radioactive Material"
  - Implementing Directive, (ID) SSD-01 "What Source and Device Designs Require an Evaluation"
  - Implementing Directive, (ID) SSD-02 "Source and Device Evaluation Technical Assistance Program"
  - Ohio Administrative Code (rules containing the information that an applicant must submit in support of a leak test frequency longer than six months)

Comments related to the Licensing Program.

24. In further reference to the "Program for the Licensing of Radioactive Materials," a procedure for a Quality Assurance (QA) assessment program should be established to improve the overall effectiveness and ensure a uniform review of licensing casework.
25. In further reference to the "Program for the Licensing of Radioactive Materials," a procedure on handling license applications involving a change of ownership should be established. 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. NRC Information Notice 89-25, Rev. 1: "Unauthorized Transfer of Ownership or Control of Licensed Activities" is suggested.
26. To enter an Agreement covering 11e.(2) byproduct material, a State needs to adopt certain procedural requirements in the licensing process related to 11e.(2) byproduct material in order to satisfy the provisions of section 274o of the Atomic Energy Act. These procedural requirements do not need to be located in the radiation control act; they may be located in the State's administrative procedures law. Section 274o should be reviewed and a statement (along with applicable citations) added to the program

description to confirm that the Ohio administrative procedures law contains the necessary procedural requirements.

27. The "Scope and Applicability" section of the "Program for the Control of Residual Radioactive Materials from Byproduct Materials as Defined in Division 3748.01(A)(2) of the Ohio Revised Code" refers to several sections of Title I of the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA). However, Title I of UMTRCA is inappropriate for referencing for the following reasons:
- a. Title I authorized the Department of Energy (DOE) to undertake a remedial action program at designated sites.
  - b. None of the designated sites are in Ohio.
  - c. Other than groundwater restoration activities at designated sites, the remedial action program will end on September 30, 1998.

The appropriate program to reference is authorized in Title II of UMTRCA.

Comments related to the inspection/compliance program.

28. In Volume 2 ("Exhibits"), Exhibit 6 ("Inspection Program for Radioactive Materials"), inspector requalification (or continuing education), and annual supervisory accompaniments of inspectors to provide management quality assurance, should be addressed.
29. In Volume 3 ("Appendices - Attachments"), Appendix 5 ("Equipment and Instrumentation"), page 1, only the Bureau's field instrumentation is described. The type and quantity of laboratory equipment available for radioactive material analysis should also be addressed.
30. In the "General Enforcement Policy," Attachment A, "Examples of Violations - Listed by Severity Level," some differences between the examples of Ohio violation severity levels and the NRC examples were noted. These 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 example items 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.

While a strict identicality of the examples of violations is not required, significant differences could lead to regulatory disparities. The examples in Attachment A should be carefully reviewed.

31. In the "Program Assessment Review," page 2, item 1, second bullet, the inspection priority of a license should not be changed based upon inspection results. The interval to the next inspection may be shortened or lengthened from the usual interval based on inspection priority in response to the inspection results.

Other comments.

32. Copies of any memoranda of understanding between the Department and any other State Agency with responsibilities related to radiation control should be added to the program description.
33. Has the Bureau adopted an internal procedure for the promulgation of rules of general applicability, or other methods to apply generic legally binding requirements (such as orders, license conditions, etc.) within three years after the amendment of NRC regulations considered important for compatibility or health and safety? If so, a statement to this effect should be added in section V.C. of the Program Narrative.
34. In the Program Narrative in Volume 1 of the application, on page 2, paragraphs 2 and 3, the references to naturally occurring and accelerator-produced radioactive materials should be removed, and a reference to the safety evaluation of SS&Ds added. Ohio already has regulatory authority over naturally occurring and accelerator-produced radioactive materials, and these radioactive materials are not subject to the Atomic Energy Act of 1954, as amended.
35. In the Program Narrative, Introduction, page 1, the sentence starting in line six is inaccurate. The State exercises independent authority and responsibility under the Agreement, not "on behalf of the NRC." NRC responsibility for the regulation of licensees in the State is terminated.
36. In the Program Narrative, Introduction, page 1, the sentence starting in line eight should indicate that the Governor must also explicitly certify that the State desires to assume the regulatory authority and responsibility.
37. In the Program Narrative, Section II(E)(2)(e), page 14, the staffing of the radiological laboratory should be discussed, or if discussed elsewhere, a reference to the staffing discussion should be given.
38. The Program Narrative, Section IV ("Development, Staffing, and Management"), subsection A ("Anticipated Licenses"), page 19, speaks of the "roll-over" of 300 NRC general licenses to State specific licenses. Please explain the term "roll-over," and indicate which NRC general licenses will be involved. It is noted that Ohio has adopted the NRC regulations for the general licenses in parts 30, 40, 70 and 71 by reference.

39. In Volume 2 ("Exhibits"), the draft agreement, page 49, subparagraph IX identifies contaminated sites as a separate category of materials. Since regulatory authority over these contaminated sites is included in the other categories of material already identified in the Agreement, the separate reference to these sites should be eliminated from the Agreement. Its inclusion is likely to cause confusion and also may raise questions regarding its consistency with §274 of the Atomic Energy Act.
40. In Volume 2 ("Exhibits"), Exhibit 10 ("Training Program for Health Physics Personnel"), on page 7, the approval authority for formal certification after completion of training requirements should be identified.
41. In the "Training Program for Health Physics Personnel", pages 7 - 9, the experience requirements for Program Administrators and Health Physics Supervisors are specified to be a minimum of three years of nuclear power plant or state government experience in applied radiation protection. This appears to be unnecessarily restrictive as it excludes those persons with experience obtained at Federal government facilities or licensee facilities other than nuclear power plants.
42. In the "Training Program for Health Physics Personnel," on page 12, consideration should be given to an "Interim Qualification" program which certifies inspectors to perform only certain types of inspections (i.e., nuclear gauges and devices).
43. The "Training Program for Health Physics Personnel," on page 13, fourth paragraph, should specify who has the authority to approve exemptions and how the exemptions granted will be documented.
44. The "Training Program for Health Physics Personnel," in Appendix A, the training matrix should have a supervisory sign-off.
45. In the "Training Program for Health Physics Personnel," Appendix A, page 5, the Oral Examination Board results should be documented.
46. In the "Training Program for Health Physics Personnel," the following NRC courses should 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)
47. In Volume 2 ("Exhibits"), Exhibit 12 ("Quality Assurance Plan for Radiological and Environmental Sampling Evolutions"), page 1, line 16, the first sentence should be expanded to indicate that the procedure includes analysis, record keeping, reporting, etc.
48. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 6, line 12, the specific document published by EPA should be referenced.

49. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 9, lines 9 - 10, if this is minimal detectable activity (MDA), it should state so, and define MDA or provide a reference.
50. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," 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.
51. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," pages 15 -16, sections 6.1 - 6.2, the software validation, ISO 9000 certification, and year 2000 problems should be addressed in these sections.
52. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 22, line 10, section 7.0, the section should be more explicit in addressing the independent verification and cross check programs.
53. The application states that both guidance and inspection procedures will be developed for decommissioning, but does not reference any documents. Such guidance and procedures are needed. The following NRC documents should be consulted in preparing the procedures:
  - "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees," NUREG/BR-0241, March 1997. This document is an overview of the decommissioning process and has numerous other references.
  - Inspection Manual Chapter 2602, "Decommissioning Inspection Program for Fuel Cycle and Materials Licensees" describes the procedures for conducting inspections of licensed facilities undergoing decommissioning.
  - Inspection Procedure 87104 for inspecting materials facilities undergoing decommissioning.

In addition, the staff has developed the following guidance to explain the new license termination rule:

- NUREG-1549, "Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination"
- NUREG-1505, "A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys"
- NUREG-1507, "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions"

## **SUGGESTIONS ON THE DRAFT APPLICATION FOR AN AGREEMENT**

### Comments related to the Sealed Source and Device Program.

1. In the SRP for SS&Ds, the definition of "active registration certificate" states that the certificate constitutes part of the basis "for the State of Ohio" to issue a license for radioactive materials. It should be added that the certificate also constitutes part of the basis for issuance of licenses by the NRC and other Agreement States.
2. In the SRP for SS&Ds, Appendix D - standard device certificate format, the custom user information should be contained on the first page of the certificate as shown in NUREG-1550, page 61.
3. In the SRP for SS&Ds, the section on Proprietary Information states that the "reviewer, upon receipt of such a marked document will make a determination with the assistance of the Program Administrator of Nuclear Materials Safety if the information is necessary to perform a safety evaluation for the product." It should be clarified how the Program Administrator will be involved in the decision, and, if it is a technical decision rather than strictly an administrative decision, why the reviewer would not be qualified to make this determination.

### Comments related to the Licensing Program.

4. In Volume 2 ("Exhibits"), Exhibit 5 ("Program for the Licensing of Radioactive Materials"), on page 8, second paragraph, the status of the license should be clarified when a renewal application is considered abandoned because a response to a deficiency letter is not received within 60 days. Does the license continue in timely renewal pending the reapplication?
5. In Volume 2 ("Exhibits"), Exhibit 5 ("Program for the Licensing of Radioactive Materials"), page 14, sixth bullet, the procedure requests the applicant to provide the page number where the sealed source or device is listed in the NRC sealed source and device (SS&D) registry. It should request the SS&D registry number.
6. In further reference to the "Program for the Licensing of Radioactive Materials," it is suggested that a procedure for assuring the security of decommissioning financial assurance instruments be established. The procedure should also address authority for drawing on decommissioning financial assurance instruments.
7. In further reference to the "Program for the Licensing of Radioactive Materials," it is suggested that a procedure be established for coordinating Bureau actions to deal with licensees that declare bankruptcy. Policy and Guidance Directive PG. 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," may be used as a guide.

ENCLOSURE 2

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7. In further reference to the "Program for the Licensing of Radioactive Materials," it is suggested that a procedure be established for coordinating Bureau actions to deal with licensees that declare bankruptcy. Policy and Guidance Directive PG. 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," may be used as a guide.

Comments related to the compliance program.

8. In reference to Volume 2 ("Exhibits"), Exhibit 7 ("General Enforcement Policy"), page 14, Table 1, it is suggested that the enforcement procedure be modified to consider the ability of the licensee to pay when assessing administrative penalties.
9. In the "General Enforcement Policy," page 17, the decision points for the administrative penalty assessment process include consideration of whether the licensee should be given credit for actions related to "identification" of the violation and if the licensee's corrective actions were "prompt and comprehensive." It is suggested that these terms be defined, with a description included of how the terms are used in the enforcement policy.
10. In Volume 3 ("Appendices - Attachments"), Attachment E ("Program Assessment Review"), page 2, item 1, first bullet, we suggest that the evaluation of core license inspections include the evaluation of the initial inspections of new licenses.

Other comments.

11. In Volume 1, "Program Narrative," the application makes reference to many old NRC guides. Consideration should be given to the use of revised and updated Regulatory Guidance, in particular, 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.)
12. In Volume 3 ("Appendices - Attachments"), Attachment E ("Program Assessment Review"), page 2, we suggest that the non-common indicators also be addressed. See NRC Management Directive 5.6.
13. In the Program Narrative, Introduction, page 1, line 15, the paragraph is unclear. It is suggested that the words "both adequate and" be deleted from line 16, and "rules and regulations" be changed to "program" in line 17.
14. In the Program Narrative, Page 16, lines 9-14, the paragraph indicates that closeout surveys will be performed at licensee facilities requesting termination of their licenses, to assure that no residual contamination has been left on site. It is suggested that this be amended to indicate that no residual contamination will be left exceeding unrestricted release limits, and to specify or reference what the unrestricted release limits are.
15. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 5, line 1, consideration should be given to having the Quality Assurance Specialist report to a higher level of program management.
16. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 6, line 9, consideration should be given to clarifying the definition of precision by expanding the discussion of "range."

17. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 6, section 3.4, this section is unclear and should be carefully reviewed.
18. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 7, line 14, section 3.6, this section also is unclear and should be carefully reviewed.
19. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 7, line 32, the term "off-site laboratory" should be defined.
20. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 8, lines 8 - 12, this paragraph should be deleted.
21. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 12, line 2, the abbreviations "AC, AT, EC, CR" should be defined.
22. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 13, line 32, we suggest the term "field quality assurance sample" be defined. Also, the definition or another explanation should indicate the use of the data.
23. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 15, lines 21 - 22, the sentence is not clear, and should be clarified or deleted as appropriate.
24. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 18, lines 20 - 21, we suggest the term "PQAC" be defined.
25. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 20, line 16, we suggest the term "Sampling Officer" be defined.
26. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 23, line 21, the term "Technical Specification" could be deleted.
27. In the "Quality Assurance Plan for Radiological and Environmental Sampling Evolutions," page 23, lines 30 and 33, this may not be sufficient time to perform a Root Cause Analysis and develop corrective actions.
28. In Volume 3, Appendix F - list of required NRC Courses -- we suggest that you list the actual MC 1246 course title and number as noted below.

Course Title Listed in Application

Actual NRC MC 1246 Course Title & #

Applied Health Physics  
Radiation Protection Engineering

Applied Health Physics (H-109)  
Site Access (H-101) or  
NMSS Radiation Worker Training (H-102)

ENCLOSURE 2

Medical Uses of Radionuclides  
 Transportation  
 Industrial Radiography  
 Materials Licensing  
 Inspection Procedures  
 Teletherapy & Brachytherapy  
 Irradiator Technology  
 Air Sampling for Radioactive Materials  
 Environmental Sampling & Analysis  
 Health Physics Technology  
 Inspecting for Performance  
 Health Physics Topical Review  
 Well Logging  
 Special Topics Workshop  
 Investigation Training  
 Regulations Workshop  
 LLW Regulators Workshop

Diagnostic & Therapeutic Nuclear Medicine (H-304)  
 Transportation of Radioactive Materials (H-308)  
 Safety Aspects of Industrial Radiography (H-305)  
 Licensing Practices & Procedures (G-109)  
 Inspection Procedures (G-108)  
 Teletherapy & Brachytherapy (H-313)  
 Irradiator Technology (H-315)  
 Air Sampling for Radioactive Materials (H-119)  
 Environmental Monitoring for Radioactivity (H-111)  
 Health Physics Technology (H-201)  
 Inspecting for Performance-Materials Version (G-304)  
 Health Physics Topical Review (H-401)  
 Safety Aspects of Well Logging (H-314)  
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 Root Cause/Incident Investigation Workshop (G-205)  
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