DATED: DEC 28, 1994; SIGNED BY: RICHARD L. BANGART

Mr. Jonathan B. Howes, Secretary
Department of Environment, Health, and
Natural Resources
3825 Barrett Drive
Post Office Box 27687
Raleigh, NC 27611-7687

Dear Mr. Howes:

This is to transmit the results of the April 18-22, 1994 NRC review of the North Carolina radiation control program relating to the State's program for performing sealed source and device (SS&D) product evaluations. The purpose of the SS&D review was to evaluate the adequacy of North Carolina's product evaluation program. The special SS&D program review was conducted by Mr. Richard Woodruff, NRC Regional State Agreements Officer, Region II, Mr. Steven Baggett, Section Leader, and Mr. Thomas Rich, Mechanical Engineer, both from the Source Containment & Devices Branch, Office of Nuclear Material Safety and Safeguards (NMSS). The review was concluded on April 22, 1994 with discussions with Mr. Dayne Brown, Director, Division of Radiation Protection (DRP); Mr. Richard M. Fry, Deputy Director, DRP; and Ms. Robin Haden, Chief, Radioactive Materials Section.

The SS&D review was conducted separately from the routine review of the State's program. The routine review was concluded on December 10, 1993 and the letter documenting the findings from this review was sent to the State on April 6, 1994. We were pleased to note that the findings from the December, 1993 routine review indicated that the State's program for the regulation of agreement materials was adequate to protect public health and safety; however, compatibility was withheld due to a regulation that the State had not adopted within the three year time frame required by NRC. We were informed that North Carolina recently adopted the amendment, making the State's program compatible at this time. In the absence of additional findings that resulted from the special SS&D review conducted in April, the North Carolina program would continue to receive an adequate finding.

As a result of the special in-depth SS&D review and the routine exchange of information between the NRC and the State of North Carolina, the staff is withholding, at this time, the finding of adequacy to protect the public health and safety. The finding of program adequacy is being withheld because of significant comments in the Category I Indicator, Adequacy of Product Evaluations. We would like to stress that the withholding of a finding of adequacy is not a finding that the State's program is inadequate to protect the public health and safety. Rather, it is a finding identifying a need to improve performance of a State's program in the areas specified which, if not addressed by the State, could lead to an inadequate program. Therefore, these findings carry potential public health and safety implications, but do not represent an immediate threat to public health and safety.

As discussed with the North Carolina radiation control staff at the conclusion of the SS&D regulatory review, we were unable to determine whether an independent product evaluation was conducted by North Carolina for sources and devices manufactured and distributed by one vendor (Troxler Electronic Laboratories, Inc.), since State files did not contain sufficient supporting background documentation and information. State personnel believed that background information, held by Troxler, and reviewed by the State was sufficient to make a licensing determination that the Troxler products were acceptable for use. The NRC staff's review of files at the Troxler facility failed to produce the necessary information to support a licensing determination. During these discussions, the North Carolina staff indicated its willingness to address this issue and to consider preparation of an action plan for conducting additional reviews of Troxler devices to provide additional bases to support existing Troxler registration certificates.

We recognize that the Troxler devices have demonstrated, by actual in-field incidents, that the source and shield will withstand typical use conditions and accidental conditions that could be encountered. However, our review was used to evaluate whether the State's program and documentation in the SS&D program were adequate to provide a supporting safety basis for acceptance of products being distributed to other licensees in the United States.

The safety significance NRC associates with SS&D reviews and the results of similar in-depth evaluations in other Agreement States may add some further perspective to our decision to withhold the finding of adequacy based on the results of this special review. Given the potential for large radiation exposures to workers or members of the public if certain devices containing radioactive materials fail, NRC strengthened its process for the review of such devices over the last several years by supplementing the traditional health physics review with mechanical engineering and material compatibility reviews. This enhanced review approach was described in a training workshop conducted in 1991 for Agreement State reviewers and in the guidance distributed at that workshop. The potential serious consequence of a device failure was underscored in 1992, when a radioactive source wire breakage at the Indiana Regional Cancer Center, Indiana, Pennsylvania, initiated a series of events that led to the unfortunate death of a patient receiving high dose rate brachytherapy treatment. Accordingly, NRC initiated a series of in-depth evaluations of Agreement State SS&D review capabilities, that included the review of the North Carolina program. Those in-depth evaluations were conducted in six Agreement States; those Agreement States perform approximately 80% of all SS&D reviews conducted by Agreement States. In all of those Agreement State SS&D program evaluations, the findings were linked to NRC's determination of program adequacy. The significant comments generated from the in-depth SS&D evaluations led, or likely will lead, to the withholding of the finding of program adequacy for three Agreement States (including North Carolina). In the other Agreement States, the comments generated by NRC reviewers were not judged to be significant, or immediate action was initiated to address program weaknesses, and a determination of program adequacy was made.

Given the significance of the results of our review, we have withheld a finding of adequacy at this time, and have identified comments and recommendations which the State needs to address. These comments and recommendations are set out in this letter and in Enclosure 2. We request specific responses from the State on these comments and recommendations, and the development of a plan to address them, as discussed in Enclosure 2, within 30 days of this letter. Once we receive and review the plan to address the comments and recommendations in the SS&D regulatory program, and have an opportunity to evaluate the actions taken to implement the plan, the NRC will

reassess the withholding of adequacy to protect public health and safety. We recognize the delay in our issuance of this letter; if you require more than 30 days to respond, please let us know.

Together with our assessment of how we have handled SS&D program in-depth review findings in other Agreement States, we have considered the nexus between the December, 1993, program review and the April, 1994, special SS&D review and whether that nexus is of sufficient significance that it should affect our withholding of a finding of adequacy. We also recognize that any in-depth review may have the appearance of using higher standards of performance than in the past. It is unfortunate that the timing of the special SS&D review was such that the program improvements noted in the December, 1993, review may receive less recognition. Although the short time between the program review and the special SS&D review is unusual, we believe, on balance, that the finding of adequacy should be based on the results of the review, rather than on the time frame in which the review was conducted. This belief primarily results from the safety significance associated with SS&D reviews performed by NRC and Agreement States. Therefore, the finding of program adequacy is being withheld.

As indicated, we are requesting that the State develop a plan that would evaluate the Troxler products to determine if any significant design or safety problems exist and what corrective actions, if any, are needed. We suggest that the State begin by evaluating the Troxler products most recently registered and the devices with the largest distribution by Troxler to obtain an increased level of confidence in the product designs. This additional confidence will allow the State to modify the action plan, if necessary, to set priorities and to make efficient use of the State's resources expended on the implementation of the action plan.

Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 is a summary of the SS&D review findings which were discussed with members of the North Carolina staff.

I appreciate the courtesy and cooperation extended to the NRC staff during the review. We view this cooperation as indicative of how the two agencies can work together. While we recognize the unique approach followed in the SS&D program evaluation, it appears that resolution of the findings will contribute to an improved radiation control program within the State of North Carolina.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc: Dayne Brown, Director
Division of Radiation Protection

Billy Cameron, State Liaison Officer

I appreciate the courtesy and cooperation extended to the NRC staff during the review. We view this cooperation as indicative of how the two agencies can work together. While we recognize the unique approach followed in the SS&D program evaluation, it appears that resolution of the findings will contribute to an improved radiation control program within the State of North Carolina.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc: Dayne Brown, Director
Division of Radiation Protection

Billy Cameron, State Liaison Officer

bcc: The Chairman
Commissioner Rogers
Commissioner de Planque

Distribution: See next page.

* See previous concurrence. ** Comments.

OFC	OSP:PM	RII:RSAO	RII:DRSS	RA:RII	OSP:DD
NME	CMaupin:gd	RWoodruff	JStohr	SEbneter	PLohaus
DTE	09/29/94*	10/4/94*	10/5/94*	10/5/94**	9/30/94*

OFC	NMSS:D	OGC	OSP:D	DEDS	EDO
NME	RBernero	FCameron	RBangart	HLThompson	JMTaylor
DTE	10/07/94*	10/21/94*	11/3/94*	11/16/94*	11/16/94* 12/16/94*

G:\CHM\94LTRSSD.NC2

Distribution:
DIR RF
EDO RF
JMTaylor, EDO
HLThompson, DEDS
DRathbun, OCA
RBernero, NMSS
FCameron, OGC
HNewsome, OGC
RBangart, OSP
PLohaus, OSP
SDroggitis, OSP
CMaupin, OSP
TCombs, OCA
DCD (SPO1) PDR (Yes_____ NO___)
NC File
SBaggett, NMSS
TRich, NMSS
SEbeneter, RII
JStohr
RWoodruff, RII
RTrojanowski, RII

Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"

The "Guidelines for NRC Review of Agreement State Radiation Control Programs," were published in the Federal Register on May 28, 1992, as an NRC Policy Statement. The Guidelines provide 30 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories. Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in several Category I indicator areas, then the need for improvements may be critical.

Category II indicators address program functions which provide essential technical and administrative support for the primary program functions. Good performance in meeting the guidelines for these indicators is essential in order to avoid the development of problems in one or more of the principal program areas, i.e., those that fall under Category I indicators. Category II indicators frequently can be used to identify underlying problems that are causing, or contributing to, difficulties in Category I indicators.

It is the NRC's intention to use these categories in the following manner. In reporting findings to State management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety and is compatible with the NRC's program. If one or more significant Category I comments are provided, the State will be notified that the program deficiencies may seriously affect the State's ability to protect the public health and safety and that the need for improvement in a particular program area(s) is critical. If, following receipt and evaluation, the State's response appears satisfactory in addressing the significant Category I comments, the staff may offer findings of adequacy and compatibility as appropriate or defer such offering until the State's actions are examined and their effectiveness confirmed in a subsequent review. If additional information is needed to evaluate the State's actions, the staff may request the information through follow-up correspondence or perform a follow-up or special, limited review. NRC staff may hold a special meeting with appropriate State representatives. No significant items will be left unresolved over a prolonged period. The Commission will be informed of the results of the reviews of the individual Agreement State programs and copies of the review correspondence to the States will be placed in the NRC Public Document Room. If the State program does not improve or if additional significant Category I deficiencies have developed, a staff finding that the program is not adequate will be considered and the NRC may institute proceedings to suspend or revoke all or part of the Agreement in accordance with Section 274j of the Act, as amended.

SUMMARY OF THE SPECIAL SEALED SOURCE AND DEVICE REVIEW OF THE
NORTH CAROLINA RADIATION CONTROL PROGRAM
APRIL 18-22, 1994

SCOPE OF REVIEW

The special in-depth sealed source and device (SS&D) regulatory program review of the North Carolina program was conducted during the period April 18-22, 1994. This aspect of the review focused on North Carolina's administrative procedures, rules, registration certificates issued during the last three years, and staffing aspects of the SS&D regulatory program. The purpose of the review was to evaluate the adequacy of the SS&D regulatory program.

The review was conducted by Mr. Richard Woodruff, Regional State Agreements Officer, Region II, Mr. Steven Baggett, Section Leader, and Mr. Thomas Rich, NRC Mechanical Engineer, both of the Source Containment & Devices Branch, Office of Nuclear Material Safety and Safeguards (NMSS).

The summary meeting was held on April 22, 1994 with Mr. Dayne Brown, Director, Division of Radiation Protection (DRP), Mr. Richard M. Fry, Deputy Director, DRP, and Ms. Robin Haden, Chief, Radioactive Materials Section.

CONCLUSION

As a result of this review, staff identified specific comments and recommendations which are set out below. The comments and recommendations in the Category I Indicator, "Adequacy of Product Evaluations," were of sufficient significance that they resulted in the withholding, at this time, of a finding of adequacy to protect public health and safety for the North Carolina Agreement State regulatory program.

STATUS OF PROGRAM

Adequacy of Product Evaluations (Category I)

NRC Guidelines

Radiation Control Program (RCP) evaluations of manufacturer's or distributor's data on sealed sources and devices outlined in NRC, State, or appropriate ANSI Guides, should be sufficient to assure integrity and safety for users. The RCP should review manufacturer's information on labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy. Approval documents for SS&D designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Comments

The special in-depth SS&D review consisted of the examination of a representative sample of new and amended registration certificates issued in the last three years for technical quality, accuracy and consistency in the following areas: format, description, labeling, diagram, conditions of use, prototype testing, radiation levels, quality assurance and quality control, limitations of use and the basis for determining that the source or device design was deemed acceptable for licensing purposes. NRC staff reviewed North Carolina's procedures to determine whether the results of the State's evaluations are sufficient to assure the protection of public health and safety, and to determine if a recommended second independent review and concurrence is performed.

During the review, seven registration certificates issued to four different vendors were examined. These registration certificates approved products for

general and specific licensing purposes and ranged from gas chromatographs containing tritium to portable moisture/density gauges containing californium-252. The NRC staff also reviewed the background information and the original documentation the North Carolina staff used to make determinations that the products were approved for licensing purposes. Based on the review of State files and discussions with the staff, the following specific comments are provided for each identified registration certificate(s).

I. Review of Troxler Devices

A. Name: Troxler
Device: Model 3400 Series
Number: NC-646-D-130-S
Date: Amended October 1991

Specific Comments:

- The SS&D files contained insufficient drawings and/or supporting documentation to make a determination about the adequacy of the State's evaluation. The State needs to obtain all the information outlined in Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Materials" and Regulatory Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Materials" from Troxler. There appears to be no well-documented basis for the State's determination that the products are acceptable for licensing purposes.

- The State should consider a method to certify that they did a radiation profile on the device and the results of the surveys.

B. Name: Troxler
Device: Model 3242
Number: NC-646-D-135-B
Date: Amended March 1992

Specific Comments:

- The SS&D files contained insufficient drawings and/or supporting documentation to make a determination about the adequacy of the State's evaluation. There appears to be no well-documented basis for the State's determination that the products are acceptable for licensing purposes.

- The certificate should list the approved source model number as stated on the source's registration certificate. If the source is to be registered as part of the device, then all necessary information needs to be reviewed and included in the registration file (i.e., materials of construction, solubility, form, welding, encapsulation, etc.). The certificate lists a Troxler drawing number with no direct reference to an approved model number.

- The State should list the type of device on the first page of the certificate under the principal use section in accordance with Regulatory Guide 10.10 or 10.11.

- Description section of the certificate needs to explain how the source is secured within the device and how the device is used (i.e., does the material to be measured pass under the device or

pass through the device?). In addition, this section should include overall dimensions of the device.

- Each certificate should include diagrams, as attachments, showing the overall dimensions of the device and safety related components (i.e., shutter mechanism, warning lamps, etc.).

- The certificate should state where and how all labels are attached (i.e., no mention of how the first label is attached).

- The certificate states that the label is in accordance with the regulations. However, a copy of the label was not included in the file.

- Prototype testing should include tests on the device, not just the transport container. The tests performed do not verify that the shielding has maintained its integrity.

- The certificate states, "Based on the melting point of the materials involved, it would take sustained temperatures of 586^{0}C to melt aluminum casing and temperatures of 1370^{0}C to melt the stainless steel source capsule." However, the polyethylene shielding for the source has a melting point lower than the 586^{0}C, which would be the limiting factor in terms of the integrity of the source as opposed to the melting points listed on the certificate for the casing and source capsule. The certificate should include the melting point of the polyethylene shielding in addition to the other melting points indicated above.

- Letter dated December 13, 1991, states that a user's manual was supplied, however, the manual could not be found. In addition, the emergency, operating or maintenance procedures could not be found.

C. Name: Troxler
Device: Model 4300 Series
Number: NC-646-D-134-S

Specific Comments:

- The SS&D files contained insufficient drawings and/or supporting documentation to make a determination about the adequacy of the State's evaluation. There appears to be no well-documented basis for the State's determination that the products are acceptable for licensing purposes.

- The certificate should list the approved source model number as stated on the source's registration certificate. If the source is to be registered as part of the device, then all necessary information needs to be reviewed and included in the registration file (i.e., materials of construction, solubility, form, welding, encapsulation, etc.). In addition, the certificate lists a Troxler drawing number with no direct reference to an approved model number.

- On the first page of the certificate, under the principal use section, the type of device should be listed in accordance with Regulatory Guide 10.10 or 10.11.

- The file only contains limited drawings for the 4350 probe.

- There was no information in the file to make an independent verification that other manufacturer's sources referenced in the background file will fit in the device, that the device will protect the integrity of the source, and whether the probe's shielding is able to withstand normal and accidental conditions of use. No parts list was provided with the 4350 probe drawing.

- The following types of questions should have been answered during the review of the files (could not answer these questions based on the file contents):

  Can the detector and source become detached during use (i.e., the detector and source are secured in the bottom section of the probe with a threaded retainer)?

  Are the probes made of material that prevents corrosion?

  How is the probe leak tested?

  Can the probe jam in the unshielded position?

- The SS&D registration certificates should include diagrams, as attachments, showing the overall dimensions of the device and all safety related components (i.e., shutter mechanism, warning lamps, etc.).

- Results and test procedures of the prototype testing performed on the device were not in the file. Prototype testing should include tests on the probes, not just the transport container. The tests performed do not verify that the shielding has maintained its integrity. How was the test for corrosion performed (i.e., certificate states that the device is designed for corrosion ranging from zero to corrosive)?

- The labels on the probes should include the model number. The national registry tracks approved sources and devices by model number.

- Adhesive labels should not be approved for use on this device.

- The SS&D registration certificates should include in the Conditions of Use and Limitations Section what length, diameter and materials of construction of the tubes that are approved for use with the probes.

- In the SS&D files, emergency, operating or maintenance procedures and/or manuals could not be found.

D. Name: Troxler
Device: Model 4430 Series
Number: NC-646-D-136-S

Specific Comments:

- The SS&D files contained insufficient drawings and/or supporting documentation to make a determination about the adequacy of the State's evaluation. There appears to be no well-documented basis for the State's determination that the products are acceptable for licensing purposes.

- The certificate should list the approved source model number as stated on the source's registration certificate. If the source is to be registered as part of the device, then all necessary information needs to be reviewed and included in the registration file (i.e., materials of construction, solubility, form, welding, encapsulation, etc.). The certificate lists a Troxler drawing number with no direct reference to an approved model number.

- On the first page of the certificate, under the principal use section, the type of device should be listed in accordance with Regulatory Guide 10.10 or 10.11.

- The file only contains limited drawings for the device.

- There was no information in the file to make an independent verification that other manufacturer's sources referenced in the background file will fit in the device, that the device will protect the integrity of the source, and whether the probe's shielding is able to withstand normal and accidental conditions of use.

- Description section states that the water content probe, which contains the neutron source, during measurement is moved from its standard shield position into a cylindrical shield of aluminum with a lead core. This shield does not appear to be adequate for neutrons. The State should review the background file to assure that the appropriate shielding is reflected in the description section of the registration certificate.

- The SS&D registration certificates should include diagrams, as attachments, showing the overall dimensions of the device and all safety related components (i.e., shutter mechanism, warning lamps, etc.).

- Results and test procedures of the prototype testing performed were not in the file. Prototype testing should include tests on the probes, not just the transport container. The tests performed do not verify that the shielding has maintained its integrity. How was the test for corrosion performed (i.e., certificate states that the device is designed for corrosion ranging from zero to corrosive)?

- The labels on the probes should include the model number. The national registry tracks approved sources and devices by model number.

- Adhesive labels should not be approved for use on this device.

- Emergency, or maintenance procedures and/or manuals could not be found. An Operation Manual was in the file, however, it needs to be updated and finalized. The version in the file references Am:Be sources not the current use of Cf-252 sources and is marked "Pending."

Troxler Recommendations:

We recommend that the State develop a plan that would evaluate the Troxler products to determine if any significant design or safety problems exist and what corrective actions, if any, are needed. We suggest that the State begin by evaluating the Troxler products most recently registered and the devices with the largest distribution by Troxler to obtain an increased level of confidence in the product designs. This additional confidence will allow the

State to modify the action plan, if necessary, to set priorities and to make efficient use of the State's resources expended on the implementation of the action plan. We have listed below areas to consider in developing this plan. Where applicable, the items listed below should also be applied to the overall SS&D program.

1. For each product evaluated and approved for use under the State's SS&D regulatory program, the State must be able to ensure that adequate and appropriate prototype testing or engineering analysis was performed by the manufacturer for the product's intended use. In addition, the manufacturer should certify that the tests were performed and that the sealed source or device passed the test. Troxler submitted information on the tests performed, but did not indicate whether or not the product passed the test. The ANSI guides should be used as a base line for the minimum set of prototype tests. However, prototype tests should be performed as deemed necessary to justify that the source housing design will maintain its integrity during normal uses and in accidental conditions.

2. The State should request and review complete operating manuals and user's manuals for device and source installations, service, maintenance, and emergency procedures to determine if any proposed activity would compromise worker safety, device integrity, or cause the licensee using Troxler devices to be in non-compliance with the State's regulations and/or requirements.

3. Detailed engineering drawings and list of materials should be provided by Troxler for all safety related components. This information is necessary to evaluate if the device/sealed source design will withstand the proposed uses (i.e., is the device design appropriate for the proposed humidity, pressure, temperature, and other proposed environmental conditions?). This information will help the reviewer gain an overall understanding of how the safety features operate. In addition, this information will also help the reviewer to evaluate any other unique safety concerns (e.g., dimensional conformity, areas of possible high friction and wear and effects of radiation on the materials).

4. All documents used to make an independent determination of acceptability must be clearly referenced. In many cases, neither the applicant nor the State knows what information was used to make the original determination of adequacy.

5. The State should obtain a legal interpretation as to whether or not the statements and background information submitted by Troxler are enforceable even though the documents are not specifically referenced in the Troxler license in tie-down conditions.

II. Review of Other Devices

A. Name: Axiom Research Corporation
Device: GC-710
Number: NC-171-D-101-G
Date: January 2, 1990

Specific Comments:

- License #092-0849-1 was terminated on 3/9/92. State should make the registration sheet inactive and address the issue of who, if anyone, accepts sources for disposal.

- 4/90 - Axiom made an address change. The operation manual and labels should have also been modified to reflect the new mailing address.

- The registration sheet should have clearly stated that this was a portable generally licensed (GL) device.

- State should review labels more carefully if they plan to use them as a limitation on the registration certificates.

- Reference section ties down a California license #3476-70GL Amendment #4, but no information was in the file for this license. Reference to documents should be clear and the documents should be available for use.

B. Name: Strandberg Engineering Laboratories
Device: MT-1405
Number: NC-581-D-101-G
Date: December 1991

Specific Comments:

- License expired on 2/28/94. The State is working on an order to terminate the license.

- Certificate format needs a lot of work, use Regulatory Guide 10.10 as the model. The current arrangement does not provide enough information. License reviewers and material inspectors need this information for license reviews and material inspections.

- Certificate authorizes the device to have 15-20% higher activity than authorized by the current license.

- During review of the applicant's submittal, the reviewer should have questioned the use of dissimilar metals. Aluminum/steel interfaces under certain conditions are subject to corrosion problems.

- The label is constructed of plastic. It may not be able to survive the typical conditions of use of the device. Therefore, the construction of the label should be reviewed prior to issuance of the registration sheet to assure that it can withstand typical use conditions. In addition, the label refers to a manual part #5459, however, the file only has a manual part #1401189; thus, the State should review the information on the label to assure that it is accurate and that it references information properly.

- To demonstrate compliance with the dose limits for products used by general licensee (10 CFR 32.51) the State should address the use of multiple source housings on a single measuring frame in its review of vendor supported dose scenarios.

- References contain only drawing numbers and no dates, which does not allow for a determination of the date of construction of the approved device and whether any changes have been made since the original construction of the device.

C. Name: Humbolt Scientific
Device: Model 5001
Number: NC-356-D-101-S
Date: Revised November 1988

Specific Comments:

- Certificate format does not follow the guidance documents.

- The source is held in place by an adhesive. Water and solvents may damage the adhesive; thus, the use of the adhesive as a securing method should be reconsidered. The State should consider having the licensee to evaluate a mechanical method of securing the source in the holder.

- The State should obtain engineering type drawings on the design of the device to show how labels are affixed and to obtain clearer details on the method used to hold the source in place.

Additional Recommendations:

The overall SS&D plan should also include the following areas in order to address the additional comments above, to enhance the utility of the SS&D registration certificates and to improve their use by other regulatory bodies.

1. The SS&D registration sheet format should follow the 1987 Regulatory Guides 10.10 and 10.11, and the 1982 sealed source and device registry user's manuals. Following this format should also help ensure performance of a complete product evaluation.

2. Although a State member and the vendor's representative sign the certificate of registration, the State should consider having another staff member independently review the product evaluation for technical content. The administrative review for typing errors and grammar is currently being done.

3. Each certificate should have as an attachment, a representative drawing(s) showing each sealed source and/or device including the overall dimensions of the device. In addition, the drawing, or another one, should be attached to the certificate which shows the safety related components (shutter, warning lamps, etc.) This information is very useful during inspection and follow-up for incidents.

4. SS&D registration certificates, which include sources that are not registered on a separate registration certificate, should contain specific information on the sources. This specific information should be equivalent to the information which should be included in a separate registration certificate for the source.

5. Deficiency letters and telephone conversation records should be included in the folder for the SS&D registration certificates so that the basis for the approval can be clearly documented.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

The NRC team members held a summary meeting on April 22, 1994 with Mr. Dayne Brown, Director, Division of Radiation Protection (DRP), Mr. Richard M. Fry, Deputy Director, DRP, and Ms. Robin Haden, Chief, Radioactive Materials Section, DRP. The specific comments developed during the device product reviews and the recommendations were discussed, and the State was asked to develop an action plan to resolve the deficiencies. In reply, Mr. Brown related that the State would be willing to develop a plan of action to resolve the concerns. However, Mr. Brown also related that while some actions could be taken in the near term, a detailed plan could not be developed or implemented until the State was provided a written report of our comments and recommendations. Mr. Brown inquired as to the significance of our findings

with respect to adequacy and compatibility. Mr. Brown was informed that the "Adequacy of Product Evaluations" was a Category I indicator, and that the review team findings would be provided to the Office of State Programs for consideration as to whether the findings would also be used for a determination of program adequacy.