



POLICY ISSUE **(Notation Vote)**

May 30, 1995

SECY-95-136

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: OPTIONS TO IMPROVE AND STANDARDIZE THE EVALUATION AND APPROVAL OF SEALED SOURCES AND DEVICES MANUFACTURED IN AGREEMENT STATES

PURPOSE:

To obtain Commission approval of a recommended option to improve and standardize the evaluation and approval of sealed source and device (SS&D) designs manufactured in Agreement States.

SUMMARY:

In 1993, following a General Accounting Office audit of the NRC's State Agreements Program and a Congressional hearing on NRC's oversight of the Agreement States, questions were raised regarding the procedures followed and the quality of evaluations performed by Agreement States for approval of SS&Ds.

In response, the staff initiated an accelerated schedule for review of Agreement State programs in this area. Findings indicate that there are variations in the quality of the SS&D evaluation programs in the Agreement States. Variations and associated concerns that were identified include inconsistencies in how manufacturers' products are reviewed, lack of design specifications for safety related components, product testing, and overall documentation of the States' evaluations of an applicant's submittal. One State lacked authority to regulate a device manufacturer located within its boundaries because the manufacturer was not a licensee of that State. The staff also noted that States without a 10 CFR 32.210 equivalent regulation could have difficulty enforcing the SS&D requirements in accordance with the statements and representations contained in the registration certificate and background file if these commitments were not tied to the manufacturer's license.

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The staff has identified four options to address these variations: (1) Reassert NRC authority over SS&D programs; (2) Provide Agreement States the option to either voluntarily relinquish their authority over SS&D programs, or retain that authority and enhance their programs; (3) Maintain current status quo of Agreement State SS&D evaluations, but enhance Agreement State SS&D programs; and 4) NRC would have sole responsibility for SS&D certificates above certain threshold values and the Agreement States would be responsible for those SS&D certificates below the threshold values. The staff recommends Option 2.

BACKGROUND:

Historically, provisions in the Atomic Energy Act (AEA) prompted a rapid increase in the number of specific license applications for SS&D use, resulting in repetitive reviews and approvals of the same products from the then small number of SS&D manufacturers. The practice of prelicensing review and approval for each item lengthened the licensing process and wasted agency resources. It also inhibited sales by requiring each applicant to resubmit product information which could already be on file in another licensee's docket. In response, the staff began cataloging the information. The catalogue became a valuable source of information about SS&Ds and a tool to avoid repetitive evaluations of the same products, particularly as the number of manufacturers grew.

In 1959 the Atomic Energy Commission (AEC) granted States, under certain conditions, the authority to regulate the use of byproduct, source and small quantities of special nuclear materials. At the time, the AEC considered the question of whether the Agreement States should assume regulatory authority over the manufacture and distribution of devices, commodities, or other products containing agreement materials under section 274b of the AEA, or whether that authority should be retained by the AEC. After considering comments on this issue, the AEC chose to reserve exclusive AEC authority over one specific category: the manufacture and distribution of products intended for use by the public on an exempt basis (10 CFR 32.14). For all other categories of manufacturers and distributors, regulatory authority would be exercised by either the AEC or the appropriate Agreement State regulatory agency.

The basis for the AEC's decision was the assumption that Agreement States would maintain compatibility with the Commission's licensing program, that there would be reciprocal recognition of licenses, and that licensing requirements among the Agreement States and the Commission would provide adequate protection of the public health and safety.

The original SS&D reference catalogue evolved into a nationwide registry of product evaluations. The registry contains summaries of the product evaluations which are referred to as registration certificates. Currently, applicants for specific licenses describe equipment by referring to data already filed with the NRC or an Agreement State by the equipment manufacturer. This practice is administratively convenient to the NRC,

Agreement States, manufacturers, and specific licensees because it reduces and simplifies paperwork.

In 1987, 10 CFR Part 30.32(g) and 10 CFR Part 32.210 codified the practice of performing "pre-marketing" evaluations and registrations of radiation safety information on certain SS&Ds. 10 CFR 32.210 detailed the type of information required from product manufacturers for approval of SS&Ds and described NRC evaluation and registration criteria. Under this system, SS&D manufacturers submit specific information on manufacturing techniques, prototype test results, and other data related to engineering and radiation safety to the NRC or the appropriate Agreement State. This information is evaluated and when it is determined that the product is safe for the proposed use, a SS&D certificate is issued.

Currently, the NRC maintains the nationwide registry of radiation safety information on SS&Ds. Regulatory authorities in the Agreement States provide copies to NRC of registration certificates they issue and have access to all certificates which have been issued and placed in the registry. Thus, when a manufacturer or distributor of products within either an Agreement or non-Agreement State provides detailed information about its sealed source or device, the results of the evaluation will be available for use in granting licensing approval to users of sources or devices throughout the United States, its territories and possessions, and Puerto Rico.

Reviews of Agreement State Sealed Source and Device Programs

Purpose of Reviews

Special in-depth reviews were conducted, mostly in 1993 and 1994, to determine whether the Agreement States have implemented programs consisting of administrative procedures, regulations and staffing that are adequate to perform SS&D product evaluations and issue SS&D registration certificates. The reviews included interaction with State staff responsible for performing the reviews to develop an understanding of their knowledge and experience in this area.

States Reviewed

In support of Office of State Program's Agreement State reviews, the Office of Nuclear Material Safety and Safeguards (NMSS) technical staff conducted SS&D evaluation program reviews in Maryland, Louisiana, California, Texas, North Carolina, and Kentucky. (Although not a part of this special review, Illinois was included with these States since NMSS staff had reviewed their SS&D program during two previous program reviews.) These seven States have issued approximately 80% of the Agreement State-generated registration certificates issued since 1987.

Procedure for Review

Two members of the Sealed Source Safety Section (SSSS), NMSS, visited each State to perform the SS&D evaluation program reviews. The staff reviewed each State's administrative procedures, rules and staffing. A representative sample of new and amended registration certificates issued in the last two years was reviewed. The reviews consisted of an in-depth examination of the registration certificates and supporting documentation 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(s) was acceptable for licensing purposes. SSSS members also reviewed the State's procedures for assurance that the results of their SS&D evaluations were consistent and that a second independent review and concurrence had been performed.

Conclusions of Review

The review identified specific areas for improvement. Several States did not have sufficient information in their specific case files to support product acceptability for licensing purposes or to support issuance of the certificate. Some State registration certificates did not contain the required information within the certificates and were not consistent with the NRC recommended format. One Agreement State did not have the authority to evaluate and approve registry certificates for the products of companies that do not possess radioactive material and are not licensed by their State. Another State reported that it could not enforce vendor commitments because the product was manufactured in another State. The need for training in the evaluation of SS&Ds, as well as the Agreement State's understanding of their role as end users of the NRC nationwide registry, was also identified.

With respect to regulations, most Agreement States do not have regulations which address the registration of product information. Under current compatibility procedures, Agreement States are not required to adopt regulations equivalent to 10 CFR 32.210 "Registration of Product Information" since this rule is a Division III item of compatibility, i.e., voluntary. 10 CFR 30.32(g), which covers applications for specific licenses for use of SS&Ds, and which refers to 10 CFR 32.210, is a Division II item of compatibility for Agreement States, i.e., the State must adopt an equivalent, or more stringent, requirement. 10 CFR 30.32(g), however, is not, by itself, sufficient since it does not contain a description of the information required to be submitted in support of a sealed source or device evaluation. This information is only described in 10 CFR 32.210. Therefore, for completeness, Agreement States should adopt both 10 CFR 30.32(g) and 10 CFR 32.210 equivalent regulations. In addition, Agreement States are also not required to adopt regulations equivalent to NRC's Part 21 which requires the reporting and analysis of defects and deviations in basic components.

Although not covered as a part of the program reviews, NRC staff notes it has also received several requests from Agreement States for technical assistance

in specific SS&D review areas where the State lacked personnel with the requisite training or experience.

DISCUSSION:

The staff has identified a need for improvement in the quality and standardization of SS&D evaluations performed by the Agreement States. The staff has developed four options found below and proposes a recommendation for Commission consideration. Attachment 1 lists the pros and cons for each option.

Option 1. NRC Assumes Sole Authority Over SS&D Programs

Under this option, NRC would reassert authority over all AEA SS&D evaluations and only the NRC would perform the safety evaluation and approval of SS&Ds containing AEA material. The NRC would issue the registry certificate and make it available for use by NRC and Agreement State staff for use in licensing.

Option 2. Agreement States Either Voluntarily Relinquish Authority Over SS&D Programs Or Retain SS&D Evaluation Authority Implementing Programs Which Meet Minimum Quality And Standardization Guidelines

This option would offer to the Agreement States the opportunity to either voluntarily return authority to NRC for evaluation of SS&Ds or to continue to evaluate SS&Ds provided that they meet a minimum set of guidelines designed to maintain a high level of quality and standardization in their evaluation programs (see Attachment 2). Meeting all key elements of the guidelines, or their equivalent, would ensure that NRC and the Agreement States have adequate programs, staffing, guidance and procedures for their SS&D evaluation programs. NRC would provide specific training for Agreement States choosing to retain the SS&D evaluation authority for the conduct of SS&D reviews. (Such training may also be of value to States that may be considering relinquishment of SS&D evaluation authority to NRC by providing them with a better understanding of the elements they would need to address in carrying out a SS&D evaluation program).

Should an Agreement State choose to voluntarily turn back the SS&D portion of their program, a letter from the Governor, requesting relinquishment of SS&D evaluation authority and assumption of that authority by the NRC would be required. Other than the request, no detailed supporting basis or rationale would be required in the request. Following receipt of the Governor's letter, the staff would prepare a Commission paper for Commission review and approval. The paper would enclose the Governor's letter and would include a proposed response to the Governor, to be signed by the Chairman, accepting the Governor's request and a proposed notice to be published in the Federal Register announcing NRC's intention to reassert SS&D evaluation authority. The letter to the Governor would include any conditions for assumption of authority and an effective date to provide for the orderly assumption of authority by the NRC.

The normal procedure for suspending or terminating an Agreement, which would include a notice and an opportunity for a hearing, would not be followed in this case since the State is voluntarily requesting that NRC reassert authority. Finally, no change would likely be required in the formal Agreement document given the general description of authority assumed by the State under the Agreement.

Option 3. Maintain Status Quo and Enhance Agreement State SS&D Programs To Ensure They Meet Minimum Quality And Standardization Guidelines

Under this option, each Agreement State would retain authority for evaluation of SS&Ds and the current practice of either NRC or Agreement State evaluation and approval of SS&Ds containing AEA material for addition to the nationwide NRC registry would continue. Manufacturers and distributors located in Agreement States would continue to submit product safety data to the appropriate Agreement State. Evaluation and approval of this data by the Agreement State would serve as a basis for the issuance of a SS&D registration certificate. Each Agreement State would be required to meet a minimum set of guidelines designed to maintain a high level of quality and standardization in their evaluation process (see Attachment 2). Meeting all key elements of the guidelines, or their equivalent, would ensure that NRC and the Agreement States have compatible regulations, adequate staffing, and guidance and procedures for their SS&D evaluation programs. NRC would provide specific training for Agreement State staff on the conduct of SS&D reviews.

Option 4. NRC Has Sole Responsibility For SS&D Certificates Above Certain Threshold Values. Agreement States Are Responsible For SS&D Certificates Below Threshold Values

Establishing a curie threshold would be a complex and somewhat subjective issue because of the wide range of variables in models used to estimate exposure pathways such as use, disposal or improper transfer. Further a threshold does not account for engineered safety features of a source or device. For example a device containing 1 curie gamma emitter can be designed to produce less exposure to its user than a device of 50 millicuries. Because the threshold would be largely dependent on the dose model, the dose limit used could be criticized as being subjective. For this reason, the staff concluded that a simpler approach is more appropriate as a screening method. While this screening method does not recognize many of the variables used in modeling, its primary focus is on external and internal dose and is based on 10 CFR Part 20 occupational exposure limits. As such this method can be quickly applied to a given application to determine if the NRC or an Agreement State will perform the safety evaluation.

The curie threshold for the screening method is developed by calculating the external dose or the ingestion/inhalation dose from a single device that would yield a 5 rem exposure. The results of a contractor study of 42 actual accidents found that the average accident is characterized by a whole body dose equivalent to exposure for 46 hours at one meter from an unshielded

source. The contractor also found that internal contamination in non-reactor type accidents is rare and the fractional in-take ranged from $2E-4$ to $2E-8$.

Using these criteria for external dose yield the results shown in Table 1 for curie threshold values.

Table 1

Isotope	Curies
Iridium-192	0.2
Cobalt-60	0.08
Cesium-137	0.3
Americium-241	8.0
Iodine-125	1.6

A 5 Rem internal dose was based on the Annual Level of Intake (ALI) in 10 CFR 20 and applying an intake fraction of $1E-4$. Multiplying the ALI by $E4$ yields a curie limit of a single source or device that a person could receive and intake if containment was lost to produce a 5 Rem internal exposure. Table 2 presents some examples.

Table 2

Isotope	Curies
Iridium-192	4
Cobalt-60	5
Cesium-137	1
Americium-241	0.008
Cadmium-109	3
Strontium-90	0.3
Iodine-125	0.4
Iron-55	90
Tritium	800

Depending on the isotope, either the external dose (Table 1) or the internal dose (Table 2) can be more limiting. Sealed sources and devices containing a greater activity for a particular isotope than is listed in either Table 1 or Table 2 would be evaluated by NRC and not the Agreement State.

Using the distribution of registration certificates produced by the States over a 6 year period of time and using this threshold approach, the staff estimates NRC would evaluate about 85% of the registration certificates generated by the Agreement States. It should be noted that applying a dose limit of 25 rem would not decrease the 85% significantly. Conversely using 100 millirem would increase the number of evaluations performed by NRC.

CRITERIA FOR ADEQUATE AND COMPATIBLE PROGRAMS:

Options 2 and 3 would require the establishment of revised minimum criteria for adequate and compatible Agreement State product evaluation programs. The staff developed a list of the key elements that make up an adequate SS&D evaluation program. The use of these elements would have the practical effect of standardizing the regulatory requirements under which SS&D manufacturers and distributors operate. Attachment 2 lists the key elements for defining an adequate SS&D evaluation program and a description for each key element. Each element plays an important role in the adequacy of the radiation control program to protect public health and safety. The elements are: 1) consistency and reliability, 2) technical accuracy, 3) evaluation of defects and incidents relating to SS&Ds, 4) communications, 5) quality assurance and quality control, and 6) inspection/enforcement. Agreement States implementing SS&D evaluation programs would require program provisions (e.g., guidance and implementation procedures) to address each element. Each necessary key element would be assessed as part of the periodic Agreement State program review to determine adequacy and compatibility.

RESOURCES:

The resources necessary to implement each option depend on a number of assumptions, including the number of Agreement States that would voluntarily return SS&D authority, or the number of SS&D certificates that may need to be reissued due to inadequate product reviews, or the lack of supporting documentation that is necessary for licensing of these products.

The staff was able to estimate resources for six activities, referred to in Table 3 as "required activities." The required activities are Technical Assistance Requests (TARs), "Hands-On" Training of Agreement State Personnel, SS&D Workshop/Course for Agreement States, SS&D-Related Activities - New, SS&D-Related Activities - Reissue and "In-Depth" Agreement State Program Reviews.

1. TARs are received from the Agreement States requesting technical assistance with reviews of products for which an applicant in their State wishes to register their product. Four TARs were received from the Agreement States last year and each TAR required approximately 2 person weeks to complete. The TARs are sent to the NRC rather than processed by the State for several reasons. One, the SS&D review may be for a device or sealed source incorporating new technologies for which no guidance, standards or policies have been issued for items that are required for the SS&D

- review (i.e., prototype testing, compatibility of materials, conditions of use). Also, the sealed source or device review may require a determination that the product meets NRC regulations (i.e., Part 34 Radiography Performance requirements) which the State has incorporated but does not have the required background on how to implement the requirements. Lastly, the State may not have the necessary expertise or resources to perform the review.
2. During the Agreement State program reviews, staff in most Agreement States requested additional training on how to perform SS&D product reviews. Although several Agreement State personnel had attended a workshop that NRC sponsored on SS&D, it was evident by their questions and concerns that additional "hands-on" training was required. In fact, there was an imperative need to provide this training to two States. These two States were provided training that required a total of approximately five weeks to complete. In addition, four of the seven programs reviewed needed improvements in their SS&D programs and NRC staff recommends that these States receive this "hands-on" training in addition to any SS&D workshops/courses. This training is specialized and varies between States and requires minimal resources from NRC (0.2-0.4 FTE/yr if all Agreement States keep SS&D reviews).
 3. As mentioned above, Agreement State personnel requested additional training on SS&D product reviews. In order for SS&D programs among the various Agreement States and the NRC to be consistent, periodic workshops/courses should be provided to the Agreement States. The workshops/courses at a minimum should cover SS&D policies and procedures, new technologies used in SS&D products, implementation of various guides and standards (i.e., ANSI guides) and incident findings with lessons learned (i.e., compatibility problems with materials).
 4. SS&D-Related Activities - New SS&D actions include technical evaluation of SS&D products and the issuance of SS&D registration certificates. In addition, it includes support for other related SS&D matters including incidents, allegations, and enforcement. Based on actual expenditures during the last year, approximately 50 SS&D actions are performed per FTE. The Agreement States perform a total of approximately 43 SS&D reviews per year.
 5. SS&D-Related Activities - Reissue includes the items mentioned in the above paragraph for SS&D actions that need to be reissued. Several of the Agreement State programs issued certificates for which there was no documentation to support the licensing of these products. Based on these program reviews the staff estimates that a maximum of 33% of the Agreement State certificates should be re-reviewed, and if appropriate, reissued.

6. The last required activity, "in-depth" program reviews, are reviews of Agreement State SS&D programs to determine if they are adequate and compatible with NRC programs. These reviews require individuals with a thorough knowledge of SS&D procedures, policies and regulations, and individuals with hands-on experience in performing numerous technical reviews of all ranges of isotopes, activities, conditions of use and technologies. These individuals will need this background to perform detailed technical reviews of Agreement State SS&D programs. Currently, it takes NRC staff a total of three weeks to complete each Agreement State program review.

Staff evaluated the possibility of contractor support for NRC activities. We are not aware of any contractors with this experience. If a contractor was chosen, it would take considerable time and effort to train them to the required level. Therefore, it is not expected that utilizing a contractor could save resources.

For any option involving the NRC dealing with vendors that historically dealt with Agreement States (Options 1, 2 and 4), workshops will be planned to provide vendor training and familiarization for efficient interaction with the NRC.

For estimation of the resources required per year, where appropriate, the required activity was averaged over a five year period (consistent with a 5 year budget). Whenever possible, the staff used actual resources expended for activities directly related to sealed sources and devices.

The additional resources needed to implement any of the options are not included in the FY 1995-1999 Five-Year Plan, nor were they included in the Internal Budget Review conducted during March and April 1995. Nevertheless, it is anticipated that the resources necessary to implement Option 2 (the staff recommended option) are available within the existing NMSS budget. The FTE utilization will be closely monitored and, if necessary, addressed in future budget activities. A summary of the resources required to implement each option is described below, and tabulated in Table 3.

Required Activities	Option 1 Min.-max.	Option 2 Min.-Max.	Option 3 Min.-Max.	Option 4 Min.-Max.
Technical Assistance Requests	-	0.1-0.2	0.1-0.2	0.1-0.2
"Hands-On" Training of Agreement State Personnel	-	0.1-0.2	0.2-0.4	0.2-0.4
SS&D Workshop/Course for Agreement State	-	0.2-0.3	0.2-0.3	0.2-0.3
SS&D-Related Activities - New	0.9-0.9	0.4-0.4	-	0.7-0.7
SS&D-Related Activities - Reissue	0.0-1.4	0.0-0.7	-	0.0-1.2
"In-Depth" Program Review	-	0.1-0.6	0.3-1.2	0.3-1.2
TOTAL	0.9-2.3	0.9-2.4	0.8-2.1	1.5-4.0

Table 3: Technical NRC Resources (FTE) Required to Implement Options

Option 1

Option 1 would require that NRC perform all technical reviews, issuance of SS&D certificates, and related activities. This effort includes interaction with Agreement States on licensing regarding certificates issued by the NRC, incident and allegation investigations, Part 21 compliance, inspection and training of vendors located in Agreement States and for training of NRC inspectors.

Agreement States perform approximately 43 SS&D evaluations per year. Technical staff resources of approximately 0.9 FTE would be required to perform these reviews. Under this option all certificates would be the responsibility of NRC. Depending on the quality of certificates already issued by the Agreement State, additional resources in the range of 0.0 to 1.4 FTE per year to reissue any inadequate certificates may be required.

The total resources required to implement this option are 0.9 - 2.3 FTE per year.

Option 2

The number of resources required to implement this option would be directly related to the number of Agreement States voluntarily returning authority to NRC. It is anticipated that most States which have not performed any SS&D reviews or have only performed a few evaluations per year will return their authority. Currently, 16 States have performed SS&D reviews.

This option assumes that the number of the Agreement States that voluntarily return their SS&D authority to NRC account for 50% of all the Agreement State certificates issued. Therefore, it is expected that in addition to the resources required to enhance SS&D programs for those States retaining authority, approximately 50% of the resources listed in Option 1 would be required to implement this option.

Enhancement of their programs requires three activities described above, "hands-on" training of Agreement State personnel, SS&D workshops/courses for Agreement States, and "in-depth" program reviews. These activities range from 0.1-0.2, 0.2-0.3, and 0.1-0.6 FTE per year, respectively. The lower end of the range assumes that those Agreement States retaining SS&D authority have adequate programs in place and require little resources to bring their programs in line with the key elements described in Attachment 2. It is expected that there will be some resources required for these activities since there will still be a need to provide periodic workshops/courses and program reviews. In addition to these resources, it is expected that the Agreement States will continue to submit TARs at the current rate, thus requiring NRC staff resources of 0.1-0.2 FTE per year.

The total resources to implement this option are 0.9-2.4 FTE per year.

Option 3

This Option assumes that Agreement States maintain SS&D authority with an enhanced program. Based on the staff's review of Agreement State SS&D programs, NRC support is necessary but varies greatly on a State by State basis and the level of effort would be proportional to the status of the State's program.

Enhancement of their program requires activities shown in Table 3 for Option 3 to implement "hands-on" training, and "in-depth" program reviews since this option does not allow for voluntary return of their SS&D program. The resources required to perform the workshop would remain (0.2-0.3 FTE per year). In addition to these resources, it is expected that the Agreement States will continue to submit TARs at the current rate, thus requiring NRC staff resources of 0.1-0.2 FTE per year.

The total resources to implement this option are 0.8-2.1 FTE per year.

Option 4

Option 4 requires the highest level of resources. Under this Option, NRC has sole responsibility for certificates above the threshold value mentioned in Tables 1 or 2. It uses the threshold value in determining which certificates should be reevaluated and reissued, depending on their quality, that were previously issued by the Agreement States. Since the Agreement State will still be responsible for those certificates below the threshold value, NRC will still provide "hands-on" training and workshops/courses to the Agreement

States. Also, since Agreement States may need to perform some SS&D reviews, NRC will need to perform "in-depth" program reviews.

The resources are estimated to be twice that for Option 2 (Option 2 assumes 50% of Agreement States return authority) for "hands-on" training of Agreement State personnel (0.2-0.4) and "in-depth" program reviews (0.3-1.2). The resources required for SS&D-related activities (new and reissuance of Agreement State certificates) would be approximately 85% (threshold value) of those listed in Option 1 (0.7, 0.0-1.2). TARs and SS&D workshops/courses would also be expected to require the same amount of resources as listed in Option 2 (0.1-0.2 and 0.2-0.3, respectively).

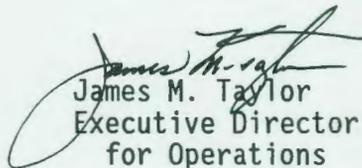
The total resources to implement this option are 1.5-4.0 FTE per year.

RECOMMENDATION:

The staff recommends that the Commission adopt Option 2. This option provides a high level of confidence that if Agreement States maintain SS&D evaluation programs these programs will be adequate to protect the public health and safety and considers the interests of the existing and future Agreement States in regulating radiological activities within their jurisdictions. Option 2 provides each Agreement State the flexibility to determine whether it wants to retain responsibility for a SS&D evaluation program, which is considered a major positive factor. Option 2 also appears to be the best option over the long term with the potential to keep NRC resource needs in this area as low as reasonably achievable. (Although Options 2 and 3 have comparable resources, the staff believes that Option 2 is preferable in that it provides Agreement States the ability to independently determine if they desire to retain SS&D evaluation authority).

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.


James M. Taylor
Executive Director
for Operations

Attachments:

1. List of Pros and Cons
2. List of Key Elements for Defining a Sealed Source and Device Evaluation Program

PRESENTATION OF
PROS AND CONS FOR EACH OPTION

Option 1 NRC Assumes Sole Authority Over SS&D Evaluations

Pros: The quality, consistency and standardization of all SS&D evaluations contained in the nationwide database would be improved since the registration certificates are likely to be more consistent when only one body is performing the evaluation.

Manufacturers would have a single set of regulations applied to the approval of all manufacturers' products including the requirements of 10 CFR Part 21 on reporting of defects and noncompliance.

License fees for SS&D manufacturers and distributors would be allocated to a larger number of NRC licensees potentially reducing the annual fee cost per licensee.

NRC programs for analysis of defects and incidents, trend analysis and determinations of possible generic problems would be improved and more efficient since all incident reports would be made to NRC and all SS&D registration certificates and background files would be stored in one location.

The technical quality of the reviews and consistency between reviewers would be expected to increase since the reviewers would be dedicated to performing reviews and working on SS&D related issues. There would be a greater likelihood that a reviewer would have seen similar devices and would be able to apply this knowledge to other evaluations.

Having a single body perform the reviews would allow more efficient implementation of any new policies and procedures that may result from products involving new technologies. Under this option, fewer reviewers would need to be trained on the new technologies.

Cons: NRC would have to absorb all of the Agreement State AEA material SS&D files and pending actions into its current program. Resources would have to be increased to manage this increase in caseload. States would still be responsible for specific use individual license reviews (custom reviews) since these reviews are specifically related to the individual licensee's health and safety program.

Agreement States that want to retain the responsibility for SS&D product evaluations would be denied that opportunity.

Manufacturers and distributors located in Agreement States would become subject to NRC license and inspection fees which would likely increase the fee costs of these licensees.

The experience base of the reviewers in Agreement States in performing a small number of NARM/NORM product evaluations would decrease due to the elimination of AEA evaluations performed by Agreement State staff and due to decreased training provided to them by the NRC.

Option 2. Agreement States Either Voluntarily Relinquish Authority Over SS&D Programs Or Retain SS&D Evaluation Authority Implementing Programs Which Meet Minimum Quality and Standardization Guidelines

Pros: Consistency and standardization of SS&D evaluations would likely improve since the evaluations would be performed by the NRC and Agreement States with strengthened programs using a single set of approved and established criteria.

The assurance that the registration certificates are technically adequate would likely be increased since the technical reviews, policies and procedures of the NRC and the Agreement States would be more consistent.

Is sensitive to the States participating in the decision by providing an opportunity for Agreement States that do not wish to continue reviewing SS&D products to return that responsibility to NRC. Conversely, it allows Agreement States that want to continue with this responsibility to do so.

Cons: Those Agreement States retaining SS&D evaluation authority would have near-term and unplanned costs associated with making changes to provide for greater consistency with NRC's program and, in some cases, technical upgrades to their programs. These changes could include the need to implement regulations or other requirements, once NRC's new adequacy and compatibility policy is established in CY 1995. The following regulations will need to be assessed using that new policy: 1) 10 CFR 30.32(g) and 32.210 on the registration of product information; and 2) 10 CFR Part 21 on the reporting and analysis of defects.

NRC would have to continue to train and provide some level of technical support to those Agreement States that retain SS&D authority and to continue program reviews. NRC resources devoted to the support of Agreement State program training, technical assistance and program review are derived from fees paid to NRC by NRC licensees.

The NRC would need to conduct product evaluations and perform inspections against 10 CFR 32.210 requirements of manufacturers and distributors in those Agreement States which return SS&D evaluation authority to the NRC.

Option 3. Maintain Current Practice And Enhance Agreement State SS&D Programs To Ensure They Meet Minimum Quality And Standardization Guidelines.

Pros: Consistency and standardization of SS&D evaluations would likely improve since the evaluations would be performed by the NRC and Agreement States with strengthened programs using a single set of approved and established criteria.

The assurance that the registration certificates are technically adequate would likely be increased since the technical reviews, policies and procedures of the NRC and the Agreement States would be more consistent.

The Agreement States could continue to utilize the reviewers performing all types of SS&D evaluations (Atomic Energy Act Materials, Naturally Occurring Radioactive Material (NORM) and Accelerator Produced Radioactive Material (NARM)). Training provided by the NRC to Agreement State personnel could also be applied by Agreement States to the evaluations of products containing NARM/NORM material.

This option allows for more efficient use of Agreement State resources for their inspections (i.e., combined inspections - manufacturing QA/QC activities, distribution license activities, possession license activities) since the Agreement States would be inspecting all licensed activities conducted by their manufacturers and distributors.

Cons: All Agreement States would have near-term and unplanned costs associated with making changes to provide for greater consistency with NRC's program and, in some cases, technical upgrades to their programs. These changes could include the need to implement regulations or other requirements, once NRC's new adequacy and compatibility policy is established in CY 1995. The following regulations will need to be assessed using that new policy: 1) 10 CFR 30.32(g) and 32.210 on the registration of product information; and 2) 10 CFR Part 21 on the reporting and analysis of defects.

NRC would have to continue to train and provide technical support to Agreement States. NRC resources devoted to the support of Agreement State program training, technical assistance and program review are derived from fees paid to NRC by NRC licensees.

Each Agreement State would have to review their own evaluations periodically to determine if any defects or incidents regarding SS&D products would affect their manufacturer's and distributor's products. They would also have to share these evaluations with NRC and other Federal, International and State agencies.

Option 4. This Option Is A Combination Of Options 1 and 2. NRC Would Have Sole Responsibility For Evaluating And Issuing Certificates On Products Above The Threshold Values Identified In Option 4. Agreement States Would Continue To Be Responsible For Those Certificates For Products Which Are Below The Threshold Values.

Pros: Consistency and standardization of SS&D evaluations would likely improve since the evaluations would be performed by the NRC and the Agreement States with strengthened programs using a single set of approved and established criteria.

The Agreement States could continue to utilize the reviewers performing SS&D evaluations (below the AEA Material threshold, Naturally Occurring Radioactive Material (NORM) and Accelerator Produced Radioactive Material (NARM)). Training provided by NRC to Agreement State personnel could also be applied by Agreement States to the evaluation of products containing NARM/NORM material.

The assurance that the registration certificates are technically adequate would likely be increased since the technical reviews, policies and procedures of the NRC and the Agreement States would be more consistent.

This option allows for more efficient use of Agreement State resources for their inspections (i.e., combined inspections for manufacturing QA/QC activities, distribution activities, possession activities) since the Agreement States would be inspecting all licensed activities conducted by a number of their manufacturers and distributors.

Cons: The Agreement States would have near-term and unplanned costs associated with making changes to provide for greater consistency with NRC's program and, in some cases technical upgrades to their programs. These changes could include the need to implement regulations or other requirements, once NRC's new adequacy and compatibility policy is established. The following regulations will need to be assessed using that new policy: 1) 10 CFR Parts 30.32(g) and 32.210 on the registration of product information; and 2) 10 CFR Part 21 on the reporting of defects and analysis of defects.

NRC would have to continue to train and provide some level of technical support to the Agreement States. NRC resources devoted to support of Agreement State program training,

technical assistance and program review are derived from fees paid to NRC by NRC licensees.

Agreement State manufacturers/distributors would be subject to both Agreement State and NRC fees for the review of their products.

Agreement State certificates which are currently in the system and exceed the threshold value may have to be re-evaluated and re-issued depending on their quality.

This option has the highest resource impact for NRC.

KEY ELEMENTS FOR DEFINING AN ADEQUATE SEALED SOURCE AND DEVICE EVALUATION PROGRAM

Based on NRC's Sealed Source Safety Section (SSSS) staff experience in matters regarding SS&D program evaluations, the NRC staff has developed a listing, including a description of key elements required for an adequate SS&D evaluation program. Each element plays an important role in the adequacy of the radiation control program to protect public health and safety. These elements are: (1) consistency and reliability, (2) technical accuracy, (3) evaluation of defects and incidents relating to SS&Ds, (4) communications, (5) quality assurance and quality control, and (6) inspection/enforcement. Each element is discussed further below. These elements provide a basis for ensuring a consistent level of protection of public health and safety in Agreement and Non-Agreement State SS&D evaluations and will be used by NRC as a basis for judging the adequacy of Agreement State SS&D evaluation programs.

1. Consistency/Reliability

The issuance of a registration certificate implies that the product, under normal conditions of use and likely accident conditions, will maintain its integrity and that the design features are adequate to protect public health and safety. Therefore, part of the registration evaluation should be used to ensure that proper prototype tests (i.e., drop test, fire test, etc.) or analyses have been performed for the normal and likely accident conditions of use, that the safety features of the device are adequate to protect public health and safety, and that all of the devices distributed will meet the same standards and specifications (QA/QC - reliability). Specific areas that need to be evaluated and summarized or contained in the registration certificate should include the product description, labeling, drawing, conditions of normal use, prototype testing, external radiation levels, quality assurance and control, limitations and/or other conditions of use, safety analysis and references.

Part of the information the license reviewer uses in making a determination as to whether an applicant can safely use the products is contained within the registration certificate. The evaluation and registration certificate must include the product's radionuclide and its activity level, the conditions of use, its design specifications (e.g., designed for a moist environment), and any limitations for the product (e.g., the product requires barriers to restrict the dose to a general licensee).

2. Technical Accuracy/Reviewer Qualifications and Training

Licensing decisions, which have a direct bearing on health and safety, are based in part on the technical information contained in the registry certificates. These certificates also serve as a vital source of information during investigations involving accidents or lost/stolen sources and devices. License reviewers, inspectors and other users of

the registry certificates rely on the assumption that an adequate technical evaluation was performed. For these reasons, there must be an adequate level of technical accuracy in each registration certificate. In order to ensure that product reviews are technically accurate, SS&D reviewers need to have the necessary qualifications and training. Reviewers should be able to: (1) understand and interpret, if necessary, appropriate prototype tests which ensure the integrity of the products under normal and likely accident conditions of use; (2) understand and interpret test results; (3) read and understand blueprints and drawings; (4) understand how the device works and how safety features operate; (5) understand and apply the appropriate regulations; (6) understand the conditions of use; and (7) understand external dose rates, source activities and nuclide chemical form.

3. Evaluation of Defects and Incidents Regarding SS&D Products

In order to provide an adequate level of assurance that workers, the public and the environment are protected from unnecessary radiation exposure, reviews of SS&D incidents should be conducted to detect possible manufacturing defects and the root causes of such incidents. Defects discovered during these reviews should be used to determine if registration certificates (approval of products for licensing) as written are: (1) adequate; (2) need to be modified; or (3) need to be withdrawn (terminated) in order to prevent licensing. The results of the reviews may indicate problems with compatibility of materials or device and source combinations or other types of problems. These results should be evaluated to determine if other products may be affected by similar problems.

4. Communications

The safe use of SS&Ds requires the clear and prompt transmittal of registration certificates among various interested parties. These include Federal and State agencies, the IAEA and the product manufacturers and distributors. Frequently SS&D evaluations and incident investigations require coordination among these parties. This is very important for products which are regulated by more than one agency.

5. Quality Assurance/Quality Control

Another part of the registration evaluation is to review the vendor's quality assurance and quality control (QA/QC) program to ensure that SS&D products are built to the same specifications as those listed on the registration certificate. This requires that vendors have and implement an adequate QA/QC program.

6. Inspection/Enforcement

To be able to protect public health and safety, inspection of product manufacturing and distribution operations and enforcement of the registrant's commitments made in their application and referenced in the registration certificate are necessary.