



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

March 26, 1999

Mr. Floyd Hamiter
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3189

Dear Mr. Hamiter:

Enclosed is our response to the "Integrated Materials Performance Evaluation Program Questionnaire." A copy of the body of the Questionnaire response and Attachment A are being sent electronically to you as requested. Please note that Attachments B through E were not available in electronic format. We look forward to your arrival. If you have any questions, please feel free to contact Larry Camper, of my staff, at 301-415-7231.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald A. Cool".

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

March 26, 1999

512-834-6688

Mr. Floyd Hamiter
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Sincerely,
(orig. signed by)
Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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OFC	MSB	C	MSB	IMNS					
NAME	MBurgess/MLB		Camper	Doer					
DATE	3/24/99		3/24/99	3/26/99					

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NRC RESPONSE TO
INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
QUESTIONNAIRE

MARCH 26, 1999

Name of Program: NRC Sealed Source and Device Evaluation Program
Reporting Period: March 1, 1995, to March 1, 1999

NON-COMMON PERFORMANCE INDICATORS: SEALED SOURCE AND DEVICE EVALUATIONS

1. A. How many registrations have been received during the review period.

FY 1995 (since 3/1/95)	109
FY 1996	172
FY 1997	145
FY 1998	165
FY 1999 (thru 3/1/99)	<u>34</u>
	608

B. Please state your goal (in days or weeks) for completing a sealed source and device safety review.

Beginning in FY 1998 (10/1/97), NRC established a timeliness goal to complete 80% of the SS&D cases received since 10/1/97, within 180 days or less. Later, NRC established a second tier to its timeliness goal, to strive to eliminate all cases greater than 1 year old by 6/30/99. Until that time, the goal was based on the quantity of actions completed each year, rather than on the turnaround time for an individual action. In most years, the goal for completions was based on the estimated number of receipts for that year. See answer 3 for additional information.

C. Please prepare a table identifying the applications for sealed source and device safety reviews that are presently overdue.

As of 3/26/99, there are 15 reviews greater than 180 days old. A list follows:

<u>Assign. #</u>	<u>Name</u>	<u>Received</u>	<u>Months Overdue</u>
97-42	Apgee Corporation	6/12/97	15 *
97-43	Apgee Corporation	6/12/97	15 *
97-44	Apgee Corporation	6/12/97	15 *
97-45	Apgee Corporation	6/12/97	15 *
97-46	Apgee Corporation	6/16/97	15 *
97-62	Universal Security Inst.	9/26/97	12 *
97-76	Apgee Corporation	12/9/97	9
97-77	Apgee Corporation	12/9/97	9
97-78	Dept. of Army	12/9/97	9
97-80	RSNP	12/19/97	9
98-02	Seaman Nuclear Corp.	1/5/98	8
98-05	Seaman Nuclear Corp.	1/6/98	8

98-39	GE Medical Systems	3/30/98	6
98-79	Hauni Richmond	7/20/98	2
98-83	Isotope Measuring Systems	8/28/98	1

* No metric existed until 10/1/97.

2. Do you have an action plan for completing the overdue safety reviews? If so, please describe the plan or provide a written copy with your response to this questionnaire.

In order to eliminate the number of overdue cases, the Sealed Source and Device program is increasing the number of signature reviewers. Three new reviewers have obtained signature authority since February 1999. In addition, cases over one year have been given priority, with a goal that as of June 99, there will be no cases over one year old.

3. Did you establish numerical goals for the number of safety reviews to be performed during this review period? If so, please describe your goals, the number of safety reviews actually performed, and the reasons for any differences between the goals and the actual number of safety reviews performed.

Yes. Until fiscal year 1998, NRC measured its performance in this area based on the number of cases completed vs. the annual goal. This annual goal was based on the amount budgeted, which was usually equivalent to the number of projected receipts. In some years the rate of actual receipts exceeded the budget projection. When this occurred, SS&D staff often worked overtime to complete more cases than the original goal. Beginning 10/1/97 (FY98), the emphasis shifted away from quantity to timeliness. (See answer 1B).

	<u>Goal</u>	<u>Actual Completions</u>
FY 1995	150	353 (from 3/1/95)
FY 1996	200	238
FY 1997	150	157
FY 1998	110	153
FY 1999	140	<u>93</u> (thru 3/1/99)
TOTAL		994

4. Please provide a staffing plan, or complete a listing of the staff, using the suggested format below. FTE refers to the professional (technical) person-years of effort applied to the sealed source and device evaluation program. Include the name, position, and the fraction of time spent performing sealed source and device reviews. Identify vacant positions. Identify senior reviewers who monitor the work of junior personnel. If consultants were used to perform sealed source and device safety reviews, include their effort also. The table heading should be:

<u>NAME</u>	<u>Name</u> <u>POSITION *</u>	<u>Position</u>	<u>Area of Effort</u> <u>FTE % FOR SS&D WORK **</u>				
			<u>FY95</u>	<u>FY96</u>	<u>FY97</u>	<u>FY98</u>	<u>FY99</u>
Broaddus	Mechanical Engineer, Regional Coordinator		1.07	1.09	1.00	0.31	0.09
Tang	Mechanical Engineer		0.49	0	0	0	0
Lubinski	Mechanical Engineer		0.88	0.56	0.42	0.38	0.14

Randall	Registration Assistant	0.13	0.19	0.07	0.21	0
Burgess	Mechanical Engineer	0.75	1.19	1.02	1.10	0.29
Perkins	Co-op	0.34	0	0	0	0
Baggett	Health Physicist	0.24	0.10	0.07	0.07	0.16
Kime	SSD Assistant	0.09	0.10	0.08	0.20	0.14
Rich	Mechanical Engineer	0.83	0.63	0.57	0	0
Smith	Nuclear Engineer	0	0.12	0.39	0.06	0
Compton	Co-op	0	0	0.47	0.77	0.09
Brown	Mechanical Engineer	0	0.67	0.58	0	0
Jankovich	Senior QA Engineer	0	0	0	0.65	0.15
Holmes	Radiation Specialist	0	0	0.01	0	0
Bhachu	Mechanical Engineer	0	0	0	0.50	0.32
Kirkwood	Health Physicist	0	0	0	0.04	0.01
Lee	Mechanical Engineer	0	0	0	0.93	0.25
TOTAL		4.83	4.65	4.67	5.42	1.56(12/31/98)

** FTE includes all SSD area activity including support work, general issues, and SSD related projects. Also includes FTE performed by staff not having signature authority, including training reviews.

See Attachment A for additional detail. With respect to vacancies, the sealed source and device program is typically budgeted about 4 FTE per year, so there were no vacancies associated with this activity in any year of this review period. However, it should be noted that senior staff members have been diverted to high priority assignments resulting in substantially less than an FTE of effort for performing signature level reviews.

Staff	<u>FTE FOR SS&D CASEWORK</u>				
	<u>FY95</u>	<u>FY96</u>	<u>FY97</u>	<u>FY98</u>	<u>FY99</u>
Signature Authority	1.23	0.94	0.54	0.46	0.22
Training Level	0.77	0.78	1.20	2.13	0.54
TOTAL CASEWORK	2.00	1.71	1.74	2.59	0.76
TOTAL SSD	4.83	4.65	4.67	5.42	1.56(12/31/98)

The following individuals have monitored the work of junior staff, or have monitored the work of staff not having signature authority: Steve Baggett, Doug Broaddus, Michele Burgess, Larry Camper, John Jankovich, John Lubinski, Charleen Raddatz, Tom Rich, and John Telford.

Regarding signature of certificates, note that although individuals in training are assigned to work on casework in order to develop and demonstrate qualifications, those individuals do not sign the certificate. All casework that is initially reviewed by an individual not having signature authority is reviewed and signed by two signature reviewers. As such, the training reviews are a training mechanism only, and do not constitute part of the safety review. Similarly, the work performed by JUPITER Corporation under contract to assist in the review process for a portion of the review period constituted support work only, and did not constitute part of the actual safety review. Since the contractor effort did not constitute part of the actual safety review and did not lead to subsequent signature authority, it is not included in the listing.

5. A. Provide the Agency's training and experience requirements for sealed source and device reviewers.

The Sealed Source and Device Training Program is going through a transition, in order to formally document the qualification program and requirements, and to more closely align the qualification program with a Manual Chapter (MC) 1246 approach. At the current time, we have implemented an interim qualification program (see "SSD Training Guidelines" in Attachment B). Further revision, in conjunction with the ongoing Sealed Source Business Process Re-engineering effort, is scheduled in Spring-Summer 99 to develop a qualification program in line with current MC 1246 approach, and will include participation by Agreement States. The goal will be to amend MC 1246 and Management Directive 5.6 to include the new program.

Prior to implementation of the above policy, training and qualifications requirements for signature authority consisted of the individual completing casework under the guidance of signature reviewers. Signature authority was obtained following demonstration by the individual, through performance of the training reviews, that the individual consistently and accurately identified and addressed all issues in accordance with the regulatory, health and safety, and policy requirements of the SSD program. The first line supervisor was responsible for monitoring the individuals progress through discussions with signature reviewers that the individual had worked under, and for providing recommendation for signature authority to management.

- B. Provide the training and experience qualifications for each reviewer who has performed sealed source and device safety reviews during the review period.

The following individuals have signed certificates during the review period, and have met the qualifications requirements in place at the time of gaining signature authority. Copies of the memoranda granting signature authority for Burgess and Rich are contained in Attachment C. The remaining memoranda will be available at the time of the onsite portion of the review.

Baggett	full signature authority - fully qualified
Broadus	full signature authority - fully qualified
Burgess	full signature authority - fully qualified
Lubinski	full signature authority - fully qualified
Rich	full signature authority - fully qualified

The following individuals have signed certificates during the review period, and have been given interim qualification in accordance with Manual Chapter 1246. See Question 5C for additional information. Copies of the memoranda granting signature authority are contained in Attachment C.

Bhachu	full signature authority, with HP restriction - interim qualification
Jankovich	full signature authority, with HP restriction - interim qualification
Lee	full signature authority, with HP restriction - interim qualification

C. For all reviewers, not meeting the agency's training and experience qualification requirements, provide a list of the courses or equivalent training/experience needed to complete these requirements or the individual's individual training plan.

Bhachu, Jankovich, and Lee received interim qualification per MC 1246, Paragraph 09, on 2/2/99. These individuals were granted interim qualification based on academic credentials, technical training, work experience, sealed source and device cases completed, and interviews to establish their qualifications journal. For additional details regarding their qualifications, see Attachment D. The only course remaining for these individuals is the 5 Week Applied Health Physics Course at ORNL, which is to be completed by 4/2/99.

D. Please identify the technical staff who left the SS&D evaluation program during the review period.

The following individuals left the program in the past four years:

**Steve Baggett, new assignment in NMSS Spent Fuel Project Office
Doug Broaddus, promotion to position in Operations Branch
Kim Randal, promotion to position in Office of Nuclear Reactor Regulation
Tom Rich, promotion to supervisory position in Office of Chief Information Officer
Michael Perkins, co-op student, returned to school
Chris Brown, rotation expired, returned to previous position
David Tang, rotation expired, returned to previous position
Brian Smith, promotion to position in Operations Branch**

6. For vacant positions, state the length of time each position has been vacant and summarize the Agency's efforts to fill the vacancy.

There is currently a Mechanical Engineer, GG-14, position posted. It is expected that this position will be filled by Summer 99. The position has been vacant since January 1998.

7. Please list all major, unusual, or complex safety reviews, or registration sheets that required a major amendment, or that were terminated under unusual situations during this period.

Due to the large number of cases completed during the review period, we are not able to provide a complete list of this information for all cases completed during the review period. The following list contains some of the cases that staff could recall involving new technology:

<u>Certificate</u>	<u>Product Type</u>
Seaman Nuclear	portable GL gauge (still under review)
Graystar	irradiator (still under review)
NR-1048-D-101-S	Transmission Attenuation Correction Source Holder
NR-1049-D-101-S	Attenuation Correction Transmission Scan Box
NR-0104-D-101-S	Transmission Line Source Holder
NR-0104-D-102-S	Transmission Line Source Holder
NR-1032-D-101-S	Transmission Line Source Holder
NR-0628-A-135-S	Radiography Collimators

NR-1025-A-101-S Control Cable Housings
NR-1054-A-101-S Rigid Guide Tube
NR-1058-A-101-S Rigid Guide Tube

8. Please list all variances in policies, procedures or exemptions from the regulations that were granted during the review period.

For certificate number NR-0186-D-117-G, the leak test requirement was exempted on the basis of staff safety analysis. The certificate indicates the exemption.

9. Please list all changes made to your written procedures during the reporting period? This would include new procedures, updates, policy memoranda, etc..

New or revised:

NUREG-1556, Volume 3 - finalized Jul. 98

(replaced Draft NUREG-1556, Vol.3 issued Sep. 97, which replaced NUREG-1550 issued Oct. 96 - both previous versions used as guidance)

Procedure to accept ISO-9000 QA certification, Dec. 98

Acceptance Review procedure, Jan. 99

Information Notice 96-20

(provides information concerning acceptable methods for licensees to demonstrate that their associated equipment used in radiographic operations meets the regulations in 10 CFR 34.20, and sets NRC policy for evaluation of this equipment..)

Withdrawn:

Regulatory Guides 10.10 and 10.11 (replaced by NUREG-1556)

10. For incidents involving failure of equipment or sources, was information on the incident provided to the sealed source and device evaluation program for an assessment of possible generic design deficiency of the device? Please provide details for each case.

NRC procedure for evaluation of incidents involving failure of equipment or sources is initiated in a number of ways. The Operations Branch at NRC Headquarters reviews the information posted in the Nuclear Materials Event Database and in Preliminary Notifications in order to identify any issues that warrant generic assessment. These items are discussed by the Generic Assessment Panel (GAP), which meets on a weekly basis. The Branch Chief responsible for the Sealed Source and Device Program is a member of GAP. The issues discussed by GAP involve all types of generic concerns and are not limited to product failures. In cases where there is insufficient information for GAP to make a determination as to the generic implications of an incident, or where more detailed or extensive technical evaluation is required, the issue is referred to staff for further evaluation, and, if necessary, resolution. An additional method of identification of product failures for evaluation by technical staff is through direct Regional involvement of Headquarters in response to an inspection finding. For incidents involving products registered in an Agreement State, the information is referred to that agency for evaluation. In incidents where there will be impact to NRC licensees, the NRC will often track the resolution of the issue in order to be alert to any actions that may be necessary on the part of NRC, for example, dissemination of information to NRC licensees, or resolution of inspection

findings involving the product.

Due to the manner that NRC handles incidents and product failures, and to the large number of instances of these occurrences, we are not able to provide a complete list of this information for all incidents or product failures reported to the NRC during the review period. The following list contains some of the incidents that were forwarded to technical staff for evaluation. Additional details regarding the resolution of these will be available through interviews with the contact and file review during the IMPEP review.

Incident	Contact
Troxler cracked insertion rods	Broaddus
Apgee model LB 300 ML/MLT bottom plate failures	Broaddus
Apgee leaking sources	Kirkwood
Hauni Richmond leaking sources	Burgess
Brachytherapy source wire failure to retract due to faulty applicator/connector	Lubinski
Failures of radiography control cables	Camper/Broaddus
Radiography drive cable connector failures	Lubinski
Several failures of self-shielded irradiators due to a lack of adequate maintenance	Broaddus
Failure of brachytherapy source wire to retract due to a bent needle applicator	Lubinski
Gauge Failure due to Excessive Vibration, early 1998 (two incidents)	Compton/Bhachu
Leaking Nuclear Associates Model 69 Brachytherapy Source, June 1998	Compton
Ruptured IR-192 Radiography Source Due to Short Circuit with Welding Equipment, June 1998	Compton/Baggett
Stuck Irradiator Source Rack at University of Michigan, April 8, 1998	Compton/Burgess
Advised State of North Carolina on SteriGenics irradiator facility cable failure	Compton
Tucker Technologies, Leaking Amersham Well Logging Source	Burgess
Radiography cameras failed to meet Part 34 requirements	Burgess
IMNS 5685 and 5749 vibration on fixed gauges	Burgess
IMNS 5674 Amersham end stop failures	Burgess
IMNS 5970 660 camera bent "S" tube	Burgess

11. Prepare a table listing new and revised SS&D registrations of sealed sources and devices issued during the review period. The table should list the new and revised sheets separately. The suggested table headings are:

<u>SS&D Registry Number</u>	<u>Manufacturer, Distributor or Custom User</u>	<u>Type of Device or Source</u>	<u>Date Issued</u>
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See Attachment E. Due to the large number of certificates issued, amended, or corrected during the review period, we have generated this listing in a different format. To identify the manufacture/distributor for each certificate, reference Attachment F.

12. Please identify all guides, standards and procedures are to be used when evaluating applications for sealed source and device registrations.

**Regulatory Guide 6.9, Feb. 95
NUREG-1556, Volume 3 - Final Report Jul. 98
Procedure to accept ISO-9000 QA certification, Dec. 98
Acceptance Review procedure, Jan. 99**