From:<julia.schmitt@hhss.ne.gov>To:<mlm1@nrc.gov>, <atm@nrc.gov>Date:08/31/2006 4:29:20 PMSubject:Fw: Nebraska's 2006 IMPEP Questionnaire

----- Forwarded by Julia Schmitt/HHSS/NEBRLN on 08/31/2006 03:21 PM -----

Bev Spang/HHSS/NEBRLN 08/31/2006 03:19 RLB@NRC.GOV PM cc Julia Schmitt/HHSS/NEBRLN@NEBRLN Subject Nebraska's 2006 IMPEP Questionnaire

Attached is Nebraska's completed 2006 IMPEP Questionnaire. Please note the organizational charts requested in item 1 are attached separately.

Please let me know if you need any additional information. Thanks.

(See attached file: 2006 IMPEP Questionnaire.doc)

(See attached file: Doc3.doc)(See attached file: Doc2.doc)(See attached file: Doc6.doc)(See attached file: Doc4.doc)(See attached file: Doc5.doc)

Bev Spang Nebraska HHS Regulation & Licensure Consumer Health Services Phone: (402) 471-2079 Fax: (402) 471-0169 **Mail Envelope Properties** (44F74696.916 : 18 : 10518)

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2006 IMPEP Questionnaire.doc	158720
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Doc5.doc	209920
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

State of Nebraska

Reporting Period: September 20, 2002, to August 31, 2006

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer if appropriate.

A. COMMON PERFORMANCE INDICATORS

I. <u>Technical Staffing and Training</u>

- 1. Please provide the following organization charts, including names and positions:
 - (a) A chart showing positions from Governor down to Radiation Control Program Director;
 - (b)

See e-mail attachments (Doc2.doc; Doc3.doc; Doc 4.doc)

(b) A chart showing positions of current radiation control program including management; and

See e-mail attachments (Doc5.doc and Doc6.doc)

- (c) Equivalent charts for sealed source and device, low level radioactive waste and uranium recovery programs, if applicable NA
- 2. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, LLW, U-mills, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

Name	Position	Area of Effort	<u>FTE%</u>
Julia Schmitt (from 01/2001)	Manager	Adminstration Licensing/Compliance	40% 20%

¹ Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the Records Management Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0183), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

		Emergency Response	10%
Sue Semerena	Administrator	Administration	10%
Jim DeFrain	HP	Licensing/Compliance Emergency Response	95% 5%
Bryan Miller	HP	Licensing/Compliance Emergency Response	95% 5%
Howard Shuman	HP	Licensing/Compliance Emergency Response	95% 5%

3. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.

No new Health Physicists were hired.

4. Please list all professional staff who have not yet met the qualification requirements of license reviewer/materials inspection staff (for NRC, Inspection Manual Chapter (IMC) 1246; for Agreement States, please enclose a copy of your qualification and training procedure. If you do not have a written procedure please describe your qualifications requirements for materials license reviewers and inspectors). For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.

All health physicists have met the training requirements for license reviewers and inspectors.

5. Please identify the technical staff who left the Agreement State/Regional DNMS program during this period.

No technical staff left the program during this period.

6. List the vacant positions in each program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

There are no vacant positions in the Radioactive Materials Program.

7. Does the Agreement State program have an oversight board or committee which provides direction to the program and is composed of licensees and other members of the public? If so, please describe the procedures used to avoid a conflict of interest.

The Nebraska Board of Health reviews proposed rules and regulations for the use of radioactive material as part of their duties. Members are required to declare in writing any matter requiring action or decision that may cause a potential conflict. A member abstains from activities in which the potential conflict exists.

II. Status of Materials Inspection Program

8. Please identify individual licensees or categories of licensees the State/Region is inspecting more or less frequently than called for in IMC 2800 and state the reason for the difference.

Program Code	Nebraska Inspection Frequency	NRC Inspection Frequency
01100	2	3
02121	3	5
02201	3	5
02220	2	3
02300	3	5
02511	3	5
03211	1	2
03214	3	5
03310	1	2
03511	3	5
03520	3	5
03610	2	3

The following categories are inspected more frequently. The frequency is based on the Program's operational experience inspecting the licensees in these categories.

9. Please provide for the review period, the number of Priority 1, 2, and 3 inspections as identified in IMC 2800 that were completed and the number of initial inspections that were completed.

This information is based on Nebraska's identified inspection priorities:
Priority 1 - 49 inspections completed
Priority 2 - 26 inspections completed
Priority 3 - 49 inspections completed
Initial Inspections Completed - 19 (these are included in the numbers above)

10. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees, and initial inspections that are presently overdue or which were conducted at intervals that exceed the IMC 2800 frequencies over the course of the entire review period. (See STP Procedure SA-101, *Reviewing the Common Performance Indicator, Status of Materials Inspection Program*, for detailed guidance in preparing this information).

At a minimum, the list should include the following information for each inspection that is overdue or conducted overdue during the review period:

- (1) Licensee Name
- (2) License Number
- (3) Priority
- (4) Last inspection date or license issued date if initial inspection
- (5) Date Due
- (6) Date Performed

(7) Amount of Time Overdue

(8) Date inspection findings issued

Licensee Name	Licensee Number	Priority	Last Inspection	Date Due	Date Performed	Time Overdue	Inspection Findings Issued
BryanLGH Medical Center	02-06-04	2	December 2, 2003	January 1, 2006	July 27, 2006	26 days	August 1, 2006

11. If you have any overdue inspections, do you have an action plan for completing them? If so, please describe the plan or provide a written copy with your response to this questionnaire.

No overdue inspections

12. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in NRC IMC 1220 and the number of candidate reciprocity inspections that were completed each year during the review period.

Calendar Year	Candidates for Reciprocity Inspections Priority 1, 2, 3	Reciprocity Inspections Completed Priority 1, 2, 3
2003	18	3
2004	23	4
2005*	14	4
2006	14	0
eletherapy and pa	anoramic irradiator service licensees were Pr	iority 1 (100%) per our procedures.
Procedures were i	updated 4/21/05.	

III. Technical Quality of Inspections

13. What, if any, changes were made to your written inspection procedures during the reporting period?

The procedures are being updated to reflect location changes of documents on the HHS servers; references changes referred to in procedures and updated forms. Procedure 3.01 "Scheduling of Inspections" was modified to reflect new inspection priorities.

14. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

Inspector	Accompanied by	License Category	Date
Jim DeFrain	Howard Shuman	Med/Edu Broad	11/5-7/2003
Bryan Miller	Howard Shuman	Med/Edu Braod	11/5-7/2003
Bryan Miller	Julia Schmitt	Nuclear Pharmacy	1/6/2004
Howard Shuman	Julia Schmitt	Irradiator	11/18/2004
Bryan Miller	Julia Schmitt	Irradiator	12/16/2004
Jim DeFrain	Sue Semerena	Industrial Gauge	8/11/2005
Bryan Miller	Jim DeFrain	Educational Broad	9/20-22/2005
Howard Shuman	Jim DeFrain	Educational Broad	9/20-22/2005
Jim DeFrain	Bryan Miller	Med/Edu Broad	4/17-19/2006
Howard Shuman	Bryan Miller	Med/Edu Broad	4/17-19/2006
Bryan Miller	Julia Schmitt	Services	5/16/2006

15. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field.

A checklist based upon information provided in the Inspection Procedures Course is utilized for accompaniments.

16. Describe or provide an update on your instrumentation, methods of calibration and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available through the review period?

The following instrumentation is available to the program:

Model 12S MicroR (1) Eberline ESP-2 with SPA-3, HP-260, HP-270, HP-210/HP-210T (2) Ludlum 2241-3 with 44-9, 44-10, 44-3 Probes and Sample Holder 180-2 FieldSpec Multi-Channel Analyzer (1) FH 40 G-L with FHZ 732 GM, FHZ 380AB, FHZ 512 Probes and SH4A (2) E-520 with HP260 Probe (3) RO-2 (2) Model 5 Geiger Counter (1) Model 14C with Probe (1) Ludlum 9 (1) Victoreen 451 (1) PAC-4S with AC-3-7 Detector (1) HP210T Probe Back-up (1)

All instruments are properly calibrated. Calibration is provided by Iowa Homeland Security and Emergency Management Division. In addition, the Ludlum Model 3, with energy compensated G-M detector (44-38) and thin crystal Nal detector (44-3) is occasionally borrowed from the x-ray program. Confirmatory wipe tests and gamma isotopic measurements can be analyzed by a contract lab. Instruments are available in sufficient number to meet the Program's needs.

IV. Technical Quality of Licensing Actions

17. How many specific radioactive material licenses does the Program regulate at this time?

Currently there are 143 specific radioactive material licenses and 6 pending license applications.

18. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period. Also identify any new or amended licenses that now require emergency plans.

The Program issued a license for a new mega-curie panoramic irradiator The Program issued a license for gamma knife use Amendments were processed for Sir-sphere and TheraSphere use All licenses are renewed in their entirety every 5 years No licenses have been required to submit an emergency plan

19. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

Exemptions are addressed by "in lieu of" conditions on the license. Several licensees have an "in lieu of" condition related to the high dose-rate remote afterloader survey and source inventory requirements. One licensee has an "in lieu of" condition related to training of new employees. One licensee has an "in lieu of" condition related to electrical interlocks. One licensee has an "in lieu of" condition related to transport container inspection. One licensee has an "in lieu of" condition related to calibration requirements and checks of dose calibrators. One licensee has an "in lieu of" condition related to release of patients treated with I-125 eye plaques.

20. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

The procedures are in the process of being updated to reflect location changes of documents on the HHS servers; references changes referred to in procedures and updated forms. Procedure 5.01 "Modified Handling Requirements for the Protection of Safeguard Information" is being added.

21. Identify by licensee name, license number and type, any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed.

Creighton University (01-82-01) Broad License - Educational

Renewal was received December 30, 2004 and this action was issued March 3, 2006. The licensee requested additional time to respond to deficiencies identified in the renewal application.

V. <u>Responses to Incidents and Allegations</u>

22. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See STP Procedure SA-300, Reporting Material Events for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

Licensee Name License # Date of Incident/Report Type of Incident

All reportable events have been reported.

23. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified? For States, was timely notification made to NRC? For Regions, was an appropriate and timely PN generated? For Agreement States, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

	Licensee Name	Lic. #	Date of event	Equipment Failure	Timely Notific ation to NRC	Was information on incident provided to the agency responsible for evaluation of the device for an assessment
a.	Bryan LGH Medical Center	02-06-03	11/13/2002	Loss Sr-90 seed	Yes	Yes
b.	BD Consumer Health Care	37-03-01	4/27/2003	Source rack failed to return to shielded position	Yes	NA
c.	Nucor Corporation	07-04-01	02/04/2005	Defective part	Yes	shield design improvement approved by Tennessee for device

- a. The licensee reported the loss of a brachytherapy Sr-90 source (model Sr0.S03) that contained an activity of 100 MBq (2.7 mCi). Both the source and the distal marker were missing from the 40-mm source train of a Novoste Beta-Cath system (model A1733, serial #85853). The device holds 16 sources and was last used on 11/13/2002. The source was determined to have been lost during the last procedure on 11/13/2002. An extensive search, that included surveys and a whole body scan of the last patient, failed to locate the missing source. The licensee determined that the source had been stuck in the catheter and discarded into the trash. The Beta-Cath system was returned to Novoste and an updated model was returned to the licensee. The cause of the lost source was the failure to perform radiation surveys prior to disposal of waste. The licensee modified their procedures to prevent a recurrence.
- b. On April 27, 2003, the Number One Source Rack failed to return to the fully shielded safe position in the pool of MDS Nordion Model JS8900 irradiator (Serial Number IR-164). The

cause was a disk attached to the source down rod caught on the protective cover of the Down Switch. This disk and rod assembly with associated tab had apparently knocked out of place by the product carriers knocking against a collision bar located adjacent to the Down Switch Cover. The tension was loosened on the guide cables in the irradiator penthouse that the source rack slides up and down on. This allowed the disk to slide off the obstruction and the rack to return to the fully shielded position.

The corrective action was to use a redundant Source Down Switch already in place and attached to the cylinder in the penthouse. The Source Rack cables were returned to the specified tension. The new switch was activated and tested under Nordion's direction. All tests were satisfactory.

- c. On 2-04-2005 the licensee (dba NUCOR Steel) reported the failure of a Berthold fixed gauge (model LB-300-ML) that contained a Co-60 source (model P 2608-100) with an activity of 0.11 GBq (3 mCi). Operators noticed that Strand Line #2 was showing erratic readings that were not consistent with the other three operating molds. Operations were suspended to investigate the cause. The assistant RSOs observed that the gauge had separated between the top actuator flange and the shield housing. It was determined that the gauge lead housing had separated from the flange, leaving approximately seven inches of the source rod unshielded. An internal and external investigation conducted by a third party revealed that the cap screws holding the shield to the actuator worked themselves loose. They believe that vibration and heat differential the gauges are exposed to loosened the cap screws. There was no visible exterior damage to the flange or housing. Leak tests and surveys were performed that verified that the gauge's actuator was locked out. The gauge was removed from service and placed in an onsite storage vault. The licensee replaced the gauge with a revised model LB-300-ML gauge in May 2005.
- 24. Identify any changes to your procedures for handling allegations that occurred during the period of this review.

The procedures are in the process of being updated to reflect location changes of documents on the HHS servers; references changes referred to in procedures and updated forms.

- VI. <u>General</u>
 - 25. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review. Provide the results of any program audits (including self audits) completed during the review period.

The IMPEP Review Team recommended that NRC's Office of Nuclear Material Safety and Safeguards review the contractor's procedure for inputting NMED data and review the database information for accuracy and completeness. Status: The NMED procedure was revised so that the contractor will acknowledge receipt of the information and provide feedback to Agreement States.

There were no recommendations given for the State.

The Program evaluates the status of inspection and licensing activities on a bi-weekly basis. All licensing actions and inspection reports receive peer and management review. Regular staff meetings are held to discuss issues.

26. Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, new initiatives, problems or difficulties which occurred during this review period.

Program Strengths:

- Prior to management review, all inspection reports and licensing actions are peer reviewed. This promotes a consistent approach among inspectors and license reviewers.
- Having experienced staff has allowed us to integrate changes, such as the Increased Controls, with minimal impact to existing regulatory responsibilities.

- Strong upper management support has allowed us to strengthen the enforcement aspect of the program.
- A robust General License Program requires licensees to annually account for generally licensed devices, including each exit sign. This has partially been responsible for influencing a large nationwide retailer to eliminate self-illuminating exit signs from their design for new stores.

Program Challenges:

 We have seen an increase in drilling for oil and gas in the western part of the state, with an associated increase in reciprocity notices for well logging. These activities often occur more than an 8 hour drive from the office on short notice. It has been difficult for us to perform reciprocity inspections on these licensees.

B. NON-COMMON PERFORMANCE INDICATORS

I. Legislation and Program Elements Required for Compatibility

27. Please list all currently effective legislation that affects the radiation control program.

Radiation Control Act 71-3501 to 71-3520 Nebraska Emergency Management Act Emergency, Governor, Civil Defense Assumption of Control of State Communication System 81-1120.25 Administrative Procedures Act 84-920 Low-Level Radioactive Waste Act 81-1578 (currently no activity)

28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

No

29. Please review and verify that the information in the enclosed State Regulation Status sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them.

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / License Condition (LC) ML # ⁴	Final State Regulation ¹ (Effective Date)
Revision of the Skin Dose Limit -Part 20	67 FR 16298; (4/5/05)	2002-1			
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (4/24/05)	2002-2			
Financial Assurance for Materials Licensees – Parts 30, 40, 70	63 FR 57327; (12/3/06)	2003-1			
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71	69 FR 3697; (10/01/07)	2004-1			
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/03)	2005-1			
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/03)	2005-2			

A Regulation Development Request has been completed and the above changes have been included in the draft regulations. Stakeholder meetings are scheduled for October. The draft regulations will then go to Governor's Policy Research Office for review followed by a public hearing. The regulations will be finalized and forwarded to the Attorney General's Office for review, then signed by the Governor.

If legally binding requirements were used in lieu of regulations, please describe their use.

Increased Controls for certain licensees were issued through the use of Orders.

30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

If statutory authority for the regulations exists, program staff drafts changes in regulations by using the Conference of Radiation Control Program Director's Suggested State Regulations, NRC Regulations, FDA, EPA and DOT regulations. The drafts are reviewed by: the Program Manager; the Consumer Safety Services Administrator; the Director of Health and Human Services, Regulation and Licensure, Regulatory Analysis and Integration Division; Legal staff; Board of Health; Attorney General's Office; and Governor's Policy Research Office. The procedures for amending regulations are outlined in "July 2001 Health and Human Services System Rulemaking Procedure Guide" which is available upon request. A general timeframe for each major step in the process outlined in the Rulemaking Procedure Guide are listed below:

Developmental Stage 30-60 days Public Hearing Stage 30-60 days Approval Stage 30 –60 days Filing State 30-60 days

Time frames may vary due to fluctuations in workload and staff availability in each stage of the process.

31. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sealed sources and devices issued during the review period. The table heading should be:

SS&D	Manufacturer,			
Registry	Distributor or	Product Type	Date	Type of
Number	Custom User	<u>or Use</u>	lssued	<u>Action</u>

NA

32. What guides, standards and procedures are used to evaluate registry applications?

NA

33. Please include information on the following questions in Section A, as they apply to the Sealed Source and Device Program:

Technical Staffing and Training - Questions 1-7 Technical Quality of Licensing Actions - Questions 17-21 Responses to Incidents and Allegations - Questions 22-24

NA

There is currently no active SS&D Program in Nebraska Health and Human Services. The Agency is prepared to contract with another Agreement State Program to perform the device review if the need arises.

III. Low-Level Radioactive Waste Disposal Program NA

34. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 1-7 Status of Materials Inspection Program - Questions 8-11 Technical Quality of Inspections - Questions 13-16 Technical Quality of Licensing Actions - Questions 17-21 Responses to Incidents and Allegations - Questions 22-24

There is currently no active Low Level Radioactive Waste Program in Nebraska Health and Human Services or in Nebraska Department of Environmental Quality. Both agencies monitor the status of low level radioactive waste nationally and advise agency management and the Governor as appropriate. NHHS and NDEQ are prepared to rebuild programs if the need arises.

IV. Uranium Recovery Program NA

35. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 1-7 Status of Materials Inspection Program - Questions 8-11 Technical Quality of Inspections - Questions 13-16 Technical Quality of Licensing Actions - Questions 17-21 Responses to Incidents and Allegations - Questions 22-24

MATERIALS REQUESTED TO BE AVAILABLE FOR THE ONSITE PORTION OF AN IMPEP REVIEW

Please have the following information available for use by the IMPEP review team when they arrive at your office:

- List of open license cases, with date of original request, and dates of follow up actions
- List of licenses terminated during review period.
- Copy of current log or other document used to track licensing actions
- Copy of current log or other document used to track inspections
- List of Inspection frequency by license type
- List of all allegations occurring during the review period. Show whether the allegation is open or closed and whether it was referred by NRC

ALSO, PLEASE HAVE THE FOLLOWING DOCUMENTS AVAILABLE:

- □ All State regulations
- Statutes affecting the regulatory authority of the state program
- □ Standard license conditions
- Technical procedures for licensing, model licenses, review guides
- □ SS&D review procedures
- □ Instrument calibration records
- □ Inspection procedures and guides
- □ Inspection report forms

- Records of results of supervisory accompaniments of inspectors
- Emergency plan and communications list
- Procedures for investigating allegations
- Procedures for investigating incidents
- Enforcement procedures, including procedures for escalated enforcement, severity levels, civil penalties (as applicable)

□ Job descriptions

Health & Human Services System



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Health & Human Services System

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Health & Human Services System Regulation & Licensure Public Health Assurance / Consumer Health Services

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