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STATE OF NEW YORK
DEPARTMENT OF HEALTH

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Dennis Sollenberger, Ph.D.
Mail Stop 0-3-H-20
Office of State Programs
US Nuclear Regulatory Commission
Washington, D.C. 20555

July 20, 1998

Dear Dr. Sollenberger:

Enclosed are our comments on the draft report "Integrated Materials Performance Evaluation Program, Review of New York Agreement State Program, January 26-April 24, 1998." These comments address editorial changes that we feel should be made to the report. We also plan to submit a separate response to the recommendations made by the team in the report.

I would like to emphasize the point that is included in the attached comments, on the need to maintain confidentiality of facilities reporting medical misadministrations to our department. This confidentiality is required by New York State Public Health Law, and therefore, we ask that all identifiers to licensees that reported such misadministrations to us be removed from the IMPEP report, as well as from all other NRC reports or documents available to the public.

If you have any questions, or need additional information, contact Steve Gavitt at 518/458-6485.

Sincerely,

310011

Karim Rimawi, Ph.D., Director
Bureau of Environmental Radiation Protection

cc: Stephen Gavitt

SP-AG-20; SP-AG-20-2

NYS Department of Health
Comments on draft IMPEP report

The following comments concern only those portions of the draft IMPEP report relating to New York State Health Department program:

Page 8 — The report indicates that there are 24 overdue inspections of new licensees (out of 34 reviewed), however there is no mention of the significance of these findings. For example, seven of these overdue inspections are former General Licensees (which are not inspected by NRC) which we decided to convert to specific licensees for tracking purposes; one is a depleted uranium licensee; three licensees where not overdue since the facilities did not have materials on-site until sometime after the license issuance date (this information is contained in the license file); and two licenses were inspected previously but a change in ownership initiated a new license to the new owners but the facilities and equipment remained unchanged.

Page 24 — The report notes that certain standard conditions are in some licenses but not others. It then goes on to indicate a potential problem - "a license reviewer informed the team that this standard condition should be put on all licenses." But it is then resolved - "As this issue was pursued, the team was then informed that this standard condition is now in the regulations." It is unclear as to the significance of the above. When a standard license condition is made into a regulation it is taken off the licenses as they are renewed. Therefore licenses that have not been renewed will have the condition until their renewal. We do not believe this is a problem.

In the same paragraph there is a focus on our "list of standard license conditions." This list is just a compilation of all various license conditions. We do not use this list to generate licenses. Licenses are not created from a blank document. Each category of license has its own "boilerplate" that is kept up to date with all applicable license conditions. When a new license condition is created, it is added to the appropriate "boilerplate" and to our list of standard license conditions. When a license condition becomes obsolete it is deleted from the boilerplate but not from the "list". So while it is true our list of standard license conditions contains outdated conditions - this does not affect our licensing process and has no significance.

Page 36 — We did adopt the "Criteria for Release of Individuals Administered Radioactive Materials" see section 16.123 of Part 16.

Appendix E-3 — Please note that NYS law prohibits the disclosure of the name of any facility that

provides reports pursuant to Part 405. Therefore you cannot print the name, location and license # for files nos. 6, 7, 8, and 9 in Appendix E-3 and we ask that these be removed from all copies of the reports and any other public documents NRC issues or maintains. File no. 1 is allowed since we took an enforcement action against this licensee and that information is available for public review.

Page 18 There are 4 field offices (Buffalo, Rochester, Syracuse and New Rochelle) and the main office.

Page 19 We do have a written training policy which was provided to the IMPEP team (copy attached).

Page 19 We only have one CHP in the program. Six others passed Part I of the certification exam last year, four of whom were eligible and took Part II this year.

BERP INSPECTOR QUALIFICATION PROCEDURE

-01 PURPOSE

01.01 To provide training guidelines for personnel to achieve initial qualification as an inspector through local, formal classroom, and on-the-job training.

01.02 To identify mandatory and optional requirements for inspectors after achieving initial inspector qualification status.

01.03 To provide additional training opportunities for the experienced inspector in identified specialty areas.

-02 OBJECTIVES

02.01 To ensure that inspectors meet minimum knowledge and qualification standard.

02.02 To provide a standardized methodology for determining that an inspector has met the minimum training requirements.

-03 POLICY

Inspector personnel must understand the facilities, processes, and activities for those areas they inspect in addition to the criteria, techniques, and mechanics of inspection. They must also be keenly aware of the potential for negative impact on safety if the inspection process is allowed to become overly intrusive in areas of operation where problems are not occurring. In addition, the inspector must be sensitized to the potential for negative regulatory impact. Newly hired personnel seldom possess all of these required qualifications. Therefore, formal classroom, self-study, and on-the-job training are needed to ensure that the newly hired inspector obtains the required knowledge and understanding necessary to be considered qualified to implement the inspection program.

Each inspector must complete the appropriate required training outlined in Appendix A of this procedure or verify, through successful completion of a written equivalency examination, that the desired level of knowledge in a particular specialty area has been obtained. Training requirements for new inspectors will be documented by the Bureau of Environmental Radiation Protection in a Qualification Journal which is identified in Appendix B of this chapter. Completion of the Training and Qualification Journal constitutes the minimum inspector qualification requirements, and encompasses regulatory, administrative, and technical practices pertinent to each area of inspection. Other requirements such as

local training may be used to supplement or enhance training. The passing grade for each course examination or equivalency examination is 70%.

Once an inspector has completed the training identified in Appendix A, that inspector will be evaluated by the appropriate Section Chief or Field Supervisor to determine that the minimum requirements are met.

In a situation where qualification is delayed as a result of an inspector not being able to schedule certain formal training courses, or for other time restraint consideration, the appropriate Section Chief, the BERP Field Supervisor or Bureau Director (or his delegate) may provide interim qualification for those areas where the inspector is considered qualified.

Inspectors who are receiving on-the-job training in preparation for meeting qualification requirements, can perform inspection activities under the direction of an inspector. With the exception of inspectors who are receiving on-the-job training, an inspector is expected to be qualified for the area being inspected. In some cases where an inspector has taken most but not all of the required training, this may require the issuance of interim qualification. An inspector who changes disciplines or is assigned to perform inspections in additional areas of discipline, must meet the training and qualifications requirements for the new discipline. It is expected that similar training requirements between disciplines will not have to be repeated, and credit for the previous similar training will be indicated in the current qualification journal.

This procedure and qualification journal are periodically revised to reflect the training needs of inspectors as determined by changes to the inspection procedures. An inspector that is qualified prior to the time any revisions are made to this procedure will continue to remain qualified. The supervisor of a qualified inspector will determine whether or not the inspector should take new courses added to this procedure as they are offered. This determination is based on the inspector's prior work experience and current inspection activities.

Special circumstances (e.g., training opportunities) may make it impossible to provide employees with required formal classroom training within the time frames specified in Appendix A. When this occurs, the appropriate Section Chief will issue a memorandum indicating the affected training courses, circumstances involved, and reinstatement dates. If a new or proposed course listed in the procedure is not available at the time an inspector has satisfied all other requirements, and the course is not critical to performing inspections as a qualified inspector, certification

may be given with the condition that the remaining course requirement be satisfied when the course is "next available."

Temporary instructions (TIs) that focus on specific "Area of Emphasis" may require special training requirements for inspectors prior to their performing the inspection. These special training requirements will be identified by the appropriate Section Chief. The schedule for preparation of any special training should allow enough lead time to prepare the required training course and implement it prior to inspection being performed using the TI.

-04 DEFINITIONS

COURSE SERIES. A progressive sequence of courses in a particular technology.

Equivalency Examination. An Examination administered in lieu of specific course attendance.

On-Site Training. Required training for inspectors designed to thoroughly acquaint the inspector with specific site systems, structures, and management organization.

Required Training. Formal classroom and on-the-job training representing the minimum acceptable level of knowledge in a given field.

Supplemental Training. Additional training courses beyond those identified for "Required Training." The additional courses will be determined by the inspector's supervisor and will depend on the inspector's previous work experience and planned inspection activities in specific area.

Refresher Training. Required training designed to update and maintain qualification.

Training and Qualification Journal. A document that establishes the minimum training requirements for formal classroom instruction, on-the-job training, local training sessions, and self-study. This document establishes the basic generic training requirements for inspector types identified in Appendix A, and lists the qualification journals in Appendix B.

Interim Qualification. Qualification of an inspector by the Bureau Director or Section Chief or Field Supervisor (or his delegate) to conduct independent inspections in specified areas of the inspection program before that inspector completes all required training.

-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Director, Bureau of Environmental Radiation Protection establishes the training requirements for inspector positions listed in Appendix A.

05.02 Section Chiefs/Field Supervisor, Bureau of Environmental Radiation Protection, ensure that inspectors achieve and maintain qualifications in accordance with the guidelines provided in this procedures.

-06 TRAINING ACTIVITIES

06.01 All staff whose principal job assignment is to perform inspections in their assigned areas of expertise, must successfully complete the training requirements for their individual inspection areas as listed in Appendix A.

a. Written examinations may be used to determine whether inspectors have obtained the 70% level of knowledge and understanding.

b. Inspectors who fail courses may be given the opportunity to acquire the knowledge level required through self-study and re-examination or to repeat the course.

c. Program management assumes that inspectors possess the necessary motivation and ability to achieve such a level of knowledge and understanding. In the rare situation where such is not the case, program management will decide what action to take on an individual basis.

06.02 classroom and simulator training are designed to supplement the inspector's education, experience, and on-the-job training by providing basic theory and knowledge as well as job related techniques.

-07 BERP TRAINING AND QUALIFICATION JOURNAL

07.01 The BERP is responsible for developing and maintaining the Training Qualification Journal. The use of the Journal is described in Appendix B of this chapter.

07.02 The BERP Journal provides the minimum training requirements to develop Training and Qualification Journals. Newly hired inspectors, except those in the intern program, will have a detailed series of activities and study areas to be completed in a specific period, usually within the first 2 years of employment.

The journals cover self-study and seminars or group discussions in the following areas:

a. Code of Federal Regulations.
b. NYSDOH regulations.
c. Pertinent inspection and environmental health manual procedures.
d. Technical areas of inspection, methods, and knowledge.
e. Schedule of orientation and required training as delineated in Appendix A.

07.03 Development, maintenance, and periodic review of these journals will be provided by the BERP.

-09 MANAGEMENT CERTIFICATION OF INSPECTOR QUALIFICATION

DOH management may, in certain circumstances, certify that an inspector is qualified to perform inspections without regard to the requirements of this procedure. The Director, Bureau of Environmental Radiation Protection will ensure the completion of the Qualification Journal including technical training and/or equivalent training.

-10 INTERIM INSPECTOR QUALIFICATION

In general, only those inspectors who have successfully completed the required training will be allowed to independently perform inspections. However, if responsible management evaluates the background and performance of an individual inspector and concludes that the inspector has demonstrated an ability to perform inspections in specific areas, even though the required training has not been completed, the Section Chief, the BERP Field Supervisor or Bureau Director, or designee as appropriate, can authorize the individual to perform inspections in those areas. When this approach is used, the successful completion of the training is still required to be completed within the time limits specified.

It is not the intent of this procedure to require persons to participate in each of the defined training activities if they already possess the type and level of knowledge that would be achieved by completing the prescribed training. If inspectors, when hired, through previous work experience and training, are deemed to possess the appropriate knowledge level for a prescribed training area, then equivalency examination(s) may be taken and thereby satisfy the training requirements. However, if work experience or previous training is determined to be equivalent to a given course, that course may be waived by appropriate management (Section Chief or Bureau Director) and a justification entered in the trainee's qualification journal.

10.01 An inspector who has not completed all requirements for final certification in one of the areas listed in A may obtain interim qualification to independently perform inspections in specified areas for which prescribed training has been completed.

10.02 To establish an interim certification, the inspector's supervisor will evaluate the inspector's qualifications and identify the portions of the inspection program for which interim qualification is appropriate.

10.03 Interim qualification will be approved by the the BERP Field Supervisor, the appropriate Section Chief or the Bureau Director, or his designee for interim qualification in the identified areas.

10.04 Approval of the interim qualification will be documented and record kept in the individual's training file.

-11 EXCEPTIONS

11.01 Inspectors, who through prior experience and education, possess sufficient knowledge to meet minimum requirements, may validate a course though satisfactory completion of an equivalency examination.

11.02 At the discretion of the Section Chief or Field Supervisor, inspectors may be qualified for certain types of inspections before they complete all of the training requirements for certification. For example, an inspector may be qualified to perform inspections of academic materials licensees before completing the specialized courses and becoming qualified for inspecting medical licenses.

11.03 The Bureau Director has the authority to waive any requirement listed for an inspector in this procedure. Justification for the waiver will be documented, and entered into the inspector's training file.

1245-12 POST QUALIFICATION TRAINING

This procedure identifies training requirements beyond those that are required for initial qualification for the experienced inspector. For the inspector who has received certification of initial qualification, mandatory and optional training requirements are identified in the sections entitled "Training Required Within Two Years of Certification," "Supplemental Training Courses, " and "Refresher Training." These sections are listed for purpose in Appendix A to this procedure. The purpose of this additional training is to recognize that inspector training does not stop with initial qualification; that training should be made available for the experienced inspector on the basis of need, special circumstances, and to keep current with the inspection program. In particular, the Fundamentals of Inspection Refresher Course (G-102) provides the inspector current views on regulatory policy and philosophy as it relates to the inspection program and the Principles of Good Regulation.

END

Appendices
1. Appendix A, Training Activities
2. Appendix B, NRC Training and Qualification Journals

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APPENDIX A

TRAINING ACTIVITIES

A. PURPOSE

To ensure that inspectors are qualified to:

1. Know their role and mission.

2. Understand the responsibilities and legal authority of an inspector.

3. Know inspection techniques and procedures and are capable of performing the inspector function.

4. Have the type and level of technical knowledge needed to adequately perform inspection activities.

5. Understand the inspection program.

B. TRAINING REQUIREMENTS

Each section of this appendix provides the inspector training requirements for a particular inspection activity as indicated below.

Section	Area of inspection
I-A	Radiation Producing Equipment Inspector
I-B	HCFA Mammography Inspector
I-C	Radioactive Materials Inspector
II-A	Next Inspector
II-B	FDA Compliance Testing Inspector

SECTION I-A
TRAINING REQUIREMENTS FOR
RADIATION PRODUCING EQUIPMENT INSPECTOR

A. APPLICABILITY

The training described below is required for all radiation producing equipment inspectors assigned to perform radiological safety inspection activities at radiation equipment registrant facilities.

B. TRAINING

1. Required initial training. This training is required for initial certification of the radiation equipment inspector.

a. Required local on-the-job training.

(1) Orientation
(2) Code of Federal Regulations (21 CFR 1000)
(3) NYSDOH Regulations (10 NYCRR 16, 76, 89)
(4) NY Public Health Law
(5) NCRP Reports No. 66, 85, 99, 100, 102, 104, 105, 107
(6) DOH Memorandums
(7) NYS Guides on Radiation Safety/Quality Assurance Programs
(8) FDA Inspection Manual
(9) Industry Codes and NIST Standards
(10) Radiological Safety Inspection Accompaniments. These include at a minimum accompaniment inspections at least two hospitals including or supplemented by at least four surveys of each of the following units: fluoroscopic, mammographic, radiographic, dental, Computerized Tomographic (CT), and non-human use other than veterinary.
(11) NYSDOH Inspection Procedures

b. Required Formal Training Courses. This training is provided in formal classroom or workshop environments and is conducted by the BERP or FDA staff or contractors.

(1) Basic Radiation Protection/Health Physics
(2) Medical X-ray Protection

2. Training Required Within Two Years of Certification. This training is required within two years of initial formal certification and is conducted by Eastman Kodak Corporation.

a. Kodak Moore 2

3. Supplemental Training Courses. Depending on the inspector's previous work experience and planned inspection activities, these additional courses may be required in order to gain knowledge necessary for specialized inspection activities. Program management will make this determination on an individual basis.

a. Accelerator Health Physics
b. Radiological Emergency Response Course
c. Radiological Accident Assessment Course
d. Enforcement Procedures

4. Refresher Training. Refresher training will be conducted as needed and as determined by management.

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SECTION I-B
TRAINING REQUIREMENTS FOR HCFA MAMMOGRAPHY SURVEYOR

A. APPLICABILITY

The training described below is required for all HCFA mammography program inspectors assigned to perform radiological safety inspection activities at HCFA mammographic facilities.

B. TRAINING

1. Required initial training. This training is required for initial certification of the radiation equipment inspector.

a. Required local on-the-job training.

(1) Orientation
(2) Code of Federal Regulations (42 CFR 494.50 to 494.64)
(3) NYSDOH Regulations (10 NYCRR 16, 76, 89)
(4) NY Public Health Law
(5) NCRP Reports No. 66, 85, 99, 100, 102, 104, 105, 107
(6) DOH Memorandums
(7) NYS Guides on Radiation Safety/Quality Assurance Programs
(8) HCFA Inspection Manual
(9) Industry Codes and NIST Standards
(10) HCFA Mammographic Survey Accompaniments. These must include at a minimum accompaniment inspections at least five HCFA mammographic surveys.
(11) NYSDOH Inspection Procedures
(12) ASPEN

b. Required Formal Training Courses. This training is provided in formal classroom or workshop environments and is conducted by the BERP or FDA staff or contractors.

(1) HCFA Mammography Certification Course

2. Training Required Within Two Years of Certification. This training is required within two years of initial formal certification and is conducted by Eastman Kodak Corporation.

a. Kodak Moore 2

3. Supplemental Training Courses. Depending on the inspector's previous work experience and planned inspection activities, additional courses may be required in order to gain knowledge necessary for specialized inspection activities. Program management will make this determination on an individual basis.

4. Refresher Training. Refresher training will be conducted as needed and as determined by management.

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SECTION I-C

TRAINING REQUIREMENTS FOR
RADIOACTIVE MATERIALS INSPECTOR

A. APPLICABILITY

The training described below is required for all radioactive materials inspectors assigned to perform radiological safety inspection activities at material licensee facilities.

B. TRAINING

1. REQUIRED INITIAL TRAINING. This training is required for initial certification of the materials inspector.

a. Required Local Training. This training is conducted in the local office using the appropriate Training and Qualification Journal.

(1) Orientation
(2) Code of Federal Regulations
(3) NYSDOH Regulations
(4) NY Public Health Law
(5) NYS DEC Regulations
(6) Updated Safety Analysis Report (if applicable)
(7) Regulatory Guidance
(8) NRC Inspection Manual
(9) Industry Codes and Standards
(10) Radiological Safety Inspection Accompaniments
(11) NRC Manual
(12) NYSDOH Inspection Procedures

b. Required Formal Training Courses. This training is provided in formal classroom or workshop environments and is conducted by USNRC staff and USNRC contractors.

(1) Health Physics (USNRC)
(2) Medical use of Radionuclides Nuclear Medicine Course (USNRC)
(3) Teletherapy (USNRC) for teletherapy inspections
(4) Inspection Procedures Course (GPA/SP) or Fundamentals of Inspection Course (G-101)

2. Training Required Within Two Years of Certification. This training is required within two years of initial formal certification and is conducted or arranged by NRC staff.

a. OSHA Orientation Course
b. Transportation of Radioactive Materials Course (H-308)
c. Internal Dosimetry & Whole Body Counting Course
d. Effective Communications for NRC Inspectors

3. Supplemental Training Courses. Depending on the inspector's previous work experience and planned inspection activities, these additional courses may be required in order to gain knowledge necessary for specialized inspection activities. Regional management will make this determination on an individual basis.

a. In-Place Filter Testing (H-105)
b. Radiological Emergency Response Course (H-303)
c. Radiological Accident Assessment Course (H-307)
d. Health Physics in Radiation Accidents Course (H-309)
e. MORT - Accident Incident Investigations Workshop (G-200)
f. MORT - Management Oversight and Risk Tree Analysis Seminar (G-201)
g. Air Sampling for Radioactive Materials (ORAU) Engineering
h. Licensing Practices and Procedures (G-109)
i. Safety Aspects of Well Logging (H-314)
j. Irradiator Technology course (H-315)
k. Environmental Sampling and Analysis Course (H-310)
l. Health Physics topical Review Course (H-401)
j. Inspecting for Performance Course (G-303)

4. Refresher Training. Refresher training will be conducted every three years following initial certification and will be determined by Regional management. Refresher training will also include the following course:

a. Fundamentals of Inspection Course (G-102)

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SECTION II-A
TRAINING REQUIREMENTS FOR NEXT SURVEYOR

A. APPLICABILITY

The training described below is required for all NEXT program inspectors assigned to perform radiological safety inspection activities at NEXT facilities.

B. TRAINING

1. Required initial training. This training is required for initial certification of the NEXT surveyor.

a. Required local training.

(1) Orientation
(2) Code of Federal Regulations (21 CFR 1000)
(3) NYSDOH Regulations (10 NYCRR 16, 76, 89)
(4) NY Public Health Law
(5) NCRP Reports No. 66, 85, 99, 100, 102, 104, 105, 107
(6) DOH Memorandums
(7) NYS Guides on Radiation Safety/Quality Assurance Programs
(8) NEXT Survey Procedures Manual
(9) Industry Codes and NIST Standards
(10) BERP Inspection Procedures

b. Required Formal Training Courses. This training is provided in formal classroom or workshop environments and is conducted by the BERP or FDA staff or contractors.

(1) NEXT Surveyor Training Course

2. Training Required Within Two Years of Certification. Not applicable.

3. Supplemental Training Courses. Each year, NEXT surveyors are expected to complete the Next Surveyor Training Course for that year since changes in inspection procedures and areas of coverage usually occur.

4. Refresher Training. Refresher training will be conducted each year as needed.

APPENDIX B

BERP INSPECTOR TRAINING AND QUALIFICATION JOURNAL

A. PURPOSE

To establish a method of conducting and documenting successful completion of the training requirements set forth in this procedure.

B. BACKGROUND

The BERP Training and Qualification Journal is designed to ensure that a uniform method of conducting and documenting training is being followed for all inspectors.

The Journal establishes the minimum training requirements that must be met for all required general and formal training courses listed in Appendix A and serves as a guide for development of other training and qualification journals (i.e., local and vendor journals).

C. BASIC REQUIREMENTS

The BERP Journal must be used to conduct and document training activities for all inspectors.

The BERP is responsible for developing and maintaining the Training and Qualification Journals. The Training and Qualification Journals included as part of this Appendix B establish the minimum requirements for a Training and Qualification Journal that must be completed for each inspector type listed in this and defined in Appendix A.