

Radiation Safety Program Audit

for

**Imaging and Sensing Technology
Corporation**

Submitted by:

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Introduction

This report is a summary of the discussions that took place during an audit of Imaging and Sensing Technology Corporation's radioactive materials safety program. The goal of the audit was to review the policies, procedures, records facilities associated with the program and provide feedback on the degree to which the program is achieving protection for workers and the environment and to offer suggestions for program enhancements.

The audit was not a comprehensive review of the program's compliance with regulatory requirements. Rather, it was a peer review process whereby the policies and methods of the program were compared to those familiar to the author. It is up to the Radiation Safety Officer and the Radiation Safety Committee to determine if the opinions and suggestions contained in this report should be adopted.

1. Program Administration

1.1 Safety Committee has written charter.

Yes.

See section I-2.0 of RSM.

1.2 Committee charter is adequate.

Yes.

1.3 Committee membership is adequate.

Yes.

Suggestion - Appoint an additional member who is appropriate to represent the company administration.

1.4 Committee meets at required frequency.

Yes.

Comment- The committee meets quarterly as specified in the RSM.

1.5 Committee documents activities and actions.

Yes.

Suggestion - Wording of committee minutes could be more explicit about decisions reached and actions taken. Also, consider using an "action list" to track progress on items selected for action by the committee.

1.6 Committee actively reviews and approves operations.

No.

Comment- The committee does not actively review operations, except those that appear on the agenda for meetings.

Suggestion - Implement a system through which the Committee issues "permits" for use of radioactive material. Permits can specify such issues as personnel, locations, inventory limits, supervisory responsibility and any special precautions deemed appropriate by the Committee. Each operation involving radioactive material has a written standard operating procedure (SOP) that the worker is trained to follow. The Committee could review these documents to see that appropriate precautions for radiation protection are included

1.7 Committee has enforcement policy or other demonstrated means of enforcement.

Yes.

Comment- Item 5 in section I-2.1 of RSM states that the committee has enforcement authority.

Suggestion - Document the decision to empower the committee with an additional communication from the company administration.

1.8 Committee reviews radiation safety program on annual basis.

Not in recent years. This audit was undertaken to correct this issue.

1.9 RSO has written definition of responsibility and authority.

Yes.

Comment- See section I-2.3 and I-3.0.

1.10 RSV's reporting structure is adequate to ensure support for both policy decisions and emergency actions.

Yes.

Suggestion - The information on the RSO's reporting structure in the current version of RSM is out of date and should be revised.

1.11 RSO receives adequate financial support for necessary operations and maintenance of professional level of knowledge.

Yes.

Comment- RSO indicates financial resources are adequate and the RSO plans to attend a professional development course within one year. A technician was recently assigned to assist with radiation safety program on a part time basis.

2. Personnel Dosimetry and Bioassay

2.1 Written procedure defines when and how personal dosimeters must be worn.

Yes.

Comment - See section II-5.1 of RSM.

Suggestion - Confirm all entrances to areas with access restrictions for radiation safety purposes are marked appropriately.

2.2 Dosimeters are provided and processed by vendor with NAWLAP certification.

Yes.

2.3 Dosimetry results reviewed by RSO in a timely manner.

Yes.

Comment - All Dosimetry reports are reviewed and initialed by the RSO.

2.4 ALARA guidelines established for doses to personnel.

Not formally.

Comment- The RSO investigates all dosimeter readings that indicate a measurable dose. This, or some other appropriate level, should be formally designated as an ALARA investigation level.

2.5 RSO follows up on dose reports that exceed the ALARA guideline.

Yes, in effect. See item 2.4.

2.6 Dosimetry results are provided to the individual.

Yes.

Comment- All dosimeter readings that indicate a measurable dose are verbally reported to the worker by the RSO.

Suggestion - Use a form letter to the worker to document 1) the RSO's investigation into the circumstances that may have caused the dose and 2) corrective actions, if any. Also, consider providing workers an annual written dosimetry summary [this may be available as a service by the dosimeter vendor].

2.7 In lab check confirms dosimeters are worn when and how they are required.

Not determined.

2.8 Written procedures define how and when bioassays are performed.

Yes.

Comment- See section II-5.2 of RSM.

Suggestion - Reword this section of the RSM to be more specific to your plant's specific operations. Have the vendor providing analysis services provide documentation of their qualifications and written procedures for collection, preservation, storage and transportation of samples. Document that these procedures are followed.

2.9 Bioassay results reviewed by RSO in a timely manner.

Yes.

Suggestion - Reports need to be initialed and dated by the RSO. Intake and/or dose need to be calculated for samples that indicate measurable radioactivity.

2.10 ALARA guidelines established for bioassay results.

Yes.

Comment- See section II-5.2 of the RSM.

2.11 RSO follows up on dose reports that exceed the ALARA guideline.

No.

Comment- ALARA guideline for bioassay results is specified as "10 percent of the Annual Limits of Intake (ALI's)". Bioassay results can not be compared directly to this criteria. The information in the report is presented as activity concentrations in the sample. This information must be converted to intake activities.

Suggestion - A method to determine intake needs to be developed.

2.12 Bioassay results are provided to the individual.

No.

3. Calibration of Radiation Detection Equipment

3.1 Inventory listing of required equipment.

Yes.

Comment- See section II-7.1 of the RSM. The current list is correct.

3.2 Calibration procedures and contractor license on file.

No.

Comment- The RSO indicated he is in the process of obtaining them from the calibration service provider.

3.3 Calibration sources NIST traceable.

Yes.

Comment- Calibration certifications on file indicate this is so.

3.4 Calibration information available to user.

Yes.

Comment- The calibration information provided to the user was not always appropriate with the use of the instrument.

Suggestion - For each radiation detection instrument, review the calibration information provided by the calibration service and the information provided to the user to be sure the calibration data and calibration sticker provide the necessary information.

3.5 Calibration frequency adequate.

Yes.

3.6 Equipment calibrated within appropriate time period.

Yes.

Comment- Data verified for two instruments. Procedures and records for instrument calibration appear well maintained.

3.7 Equipment checked for proper operation during use (check source).

Yes for some units, not on others.

Comment- RSO confirmed he is in the process of obtaining more check sources.

Suggestion - As part of annual retraining, remind workers of the procedure for checking proper operation.

4. Training

4.1 Content of training program is documented.

Yes.

Comment- See *Radiation Safety Training Manual* dated December 1994. Course outline was attached to sign-in sheets for each training program. Each operation involving radioactive material has a written standard operating procedure (SOP) that the worker is trained to follow.

4.2 Content of training program is adequate.

Yes.

4.3 Attendance at training program is documented.

Yes.

4.4 Effectiveness of training is documented (test results).

No.

Comment- The RSO indicated he planned to re-institute the practice of requiring each worker using radioactive material to pass a quiz based on the material contained in the radiation safety training program.

4.5 In lab check confirms effectiveness of training.

Not evaluated.

5. Un-sealed Material Inventory

5.1 RSO tracks on-hand inventory and maintains levels within license limits.

Yes.

Comment- The quantity of radioactive material on-hand is tallied every 4 to 6 months and prior to giving approval to purchase new material.

Suggestion - Confirm the on-hand inventory on a monthly or quarterly basis. Include all items in storage for disposal.

5.2 In lab checks confirm inventory is accurate.

Yes.

Suggestion - Review all procedures for tracking amount of radioactive material uses and on hand with the individuals keeping these records. Confirm that the procedures would catch situations where an unauthorized or un-recorded use had taken place (ex. a slow leak from a gas cylinder).

6. Sealed Source Wipe Test & Inventory

6.1 RSO maintains up-to-date list of all sealed sources.

Yes.

Comment - The list is maintained as part of the RSM.

Suggestion - If the list of all sealed sources were maintained apart from the RSM, it would be easier to up-date.

6.2 Wipe tests and inventory checks for all sources made at the required frequency.

Yes.

Comment - Frequency is 6 months. Wipe tests taken July 8, 1997 - results still pending.

Wipe tests taken January 22, 1997 - results dated 2/20/97. Wipe tests taken July 12, 1996 - report dated 7/22/96.

6.3 Labeling, signage and security adequate for all sources.

Not determined.

6.4 Documentation of wipe test results is adequate.

Yes for some reports, but not for all.

Comments - The format of wipe test analysis reports changed between 7/22/96 and 2/20/97. The latter report, the results do not indicate the total activity determined for the sample.

Suggestion - RSO needs to indicate on each report that the results for each source are or are not satisfactory. The report format should indicate the total activity determined per wipe. Leak tests are not required for sources #11 and #12 because of their low activity.

6.5 Follow up action taken as needed.

No follow-up action has been needed.

7. Compliance Inspections of Radioactive Material Use Areas

7.1 Inspections of use area are performed routinely.

No.

Suggestion - An inspection program should be developed and carried out on a quarterly or semi-annual basis. One individual should be designated as responsible for maintaining compliance with inspection criteria. Prior to initiating inspection program, the inspection criteria should be explained to the individuals responsible for maintaining compliance.

7.2 Inspections are properly documented.

No.

7.3 Inspections cover appropriate items.

No.

7.4 Inspections are reviewed by RSO.

No.

7.5 Follow up, if needed, is carried out.

No.

7.6 See inspection report for individual areas for results of inspection conducted by this auditor.

Inspection conducted of Mounting Room Area 12. See attached report.

8. Radiation Protection Surveys of Radioactive Material Use Areas

8.1 Surveys of use area are performed routinely.

Yes.

8.2 Surveys are properly documented.

Wipe test surveys satisfactory. Improvement needed for meter surveys.

Suggestion - A written procedure should be developed for how surveys are performed. Survey data sheets should identify the radiation detection instrumentation used for the survey. Survey reports should show results in DPM and mrem/h.

8.3 Surveys are reviewed by the RSO.

Yes.

Suggestion - The RSO should indicate whether results are or are not satisfactory.

8.4 Follow up, if needed, is carried out.

Yes.

Comments - Records show the results of both pre and post decontamination results.

9. Waste Management

9.1 Waste management procedures in place for all operations.

Yes.

Comment - SOP's explain how to handle radioactive waste.

Suggestion - The Radiation Safety Committee should review SOP's to determine that waste procedures are adequate.

9.2 Procedures provide waste minimization.

Yes.

Comment - The licensee uses re-distillation and evaporation to reduce waste volumes.

9.3 Waste storage procedures minimize possibility of spills or improper handling.

Improvement needed.

Suggestion - Require secondary containment for containers of liquids. Line trash containers with disposable plastic liners.

9.4 In lab checks confirm workers familiar with waste procedures.

Yes.

Comment - Based on a discussion with one worker in the Mounting Room.

9.5 Waste is collected at an appropriate frequency.

Yes.

Comment - One full container found in the Mounting Room with a date of 1995.

9.6 Waste is transported and/or stored in an appropriate manner.

Yes.

9.7 If practiced, disposal to the sanitary sewer is documented and conforms to applicable regulations.

No waste is added to the sanitary sewer.

9.8 Waste is transferred to licensed facility via a licensed broker.

Yes.

10. Authorization of Users and Operations of Radioactive Material

10.1 Standardized approval process.

Operations involving radioactive material are covered by SOP's. Some of these are reviewed by the RSO.

All users receive radiation safety training prior to being allowed to work in any radioactive material use area.

Suggestion - Develop a more formal process for the radiation safety committee to approve all use of radioactive material. See suggestion for item 1.6. The review should take place prior to the initiation of any new procedure and take place periodically to confirm that operations continue to follow committee requirements.

10.2 Written operating procedures.

Exist for some operations.

Suggestion - The Radiation Safety Committee should review all SOP's that involve the use of radioactive material and ensure that they address radiation safety adequately.

10.3 Responsibility for compliance delegated to specific individual.

No.

Suggestion - Designate one specific individual to supervise each area where radioactive material is used.

10.4 Authorizations for selected areas reviewed and adequate.

No.

10.5 In lab check confirms compliance with conditions of authorization.

Not reviewed.

11. Emergency Response

11.1 Responsibility for emergency planning is delegated to a specific individual.

Yes, the RSO.

11.2 Potential emergency situations documented.

No.

11.3 Emergency plan and procedures are appropriate to the potential for emergency situations.

No.

11.4 All internal and external groups with responsibility for emergency response have confirmed their willingness to fulfill their part in the emergency plan.

Need for improvement.

Comments - Local hospital and fire department are aware that radioactive materials are used at the facility. Additional planning for emergency situations is recommended.

11.5 All material and equipment needed to carry out the emergency plan is in place ready for immediate use.

Yes.

11.6 Contents of emergency supplies checked on regular basis.

No.

11.7 Drills or other training activities are conducted with all groups at the appropriate frequency.

No.

- 11.8 Appropriate emergency procedures, including up-to-date contact numbers, are posted in all use areas.**

Yes.

- 11.9 Actual emergency situations, if any, are documented, reviewed to determine if changes are needed in the plan. If so, changes are implemented.**

No emergency situations have occurred.

12. Receiving of Radioactive Material

- 12.1 All orders for radioactive material receive prior approval of RSO.**

Yes.

- 12.2 Records of previous orders confirm RSO approves all orders in advance.**

Yes.

Comment - Purchase requests for radioactive material must be signed by the RSO before the Purchasing Department will act on them.

- 12.3 Written procedures available for opening incoming packages.**

Yes.

Comment - See section II-11a&b of the Radiation Safety Manual.

- 12.4 Procedures are adequate.**

Yes.

- 12.5 Arrangements are made for off-hours deliveries.**

Yes. No shipments are accepted after hours.

- 12.6 Records of past shipments confirm all are received in a manner consistent with procedures.**

No.

Procedures and form for receiving only recently instituted.