



Standard Imaging, Inc.
WI DNR Green Tier I Certification
Annual Report for 2014
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Submitted by Raymond T. Riddle, PE, RAC, Chief Regulatory Officer and Co-founder.

Company Overview

Standard Imaging has shown, time and again, an astonishing ability to define or capture niche, but important, medical physics and radiation cancer treatment support markets. The company now has products in 98 of the top 100 cancer treatment centers in the U.S. The acceptance of Standard Imaging's products has resulted in continued growth, commercial distribution in more than 80 countries, inclusion in more than 300 scientific publications and numerous awards. Patients are primary beneficiaries of the products and efforts of the company, as improvements in radiation quality assurance help to ensure the safe delivery of therapeutic radiation treatments. This focus drives Standard Imaging to produce each product with the belief that it could one day be used on a family member.

Standard Imaging, Inc. is a privately held corporation founded in 1989, by four individuals, three of whom remain owners and are active in the operation of the company. These individuals bring a total of more than 90 years experience in the medical device industry to the company. In the past 22 years, Standard Imaging has steadily grown from its humble beginnings in a founder's basement to become a prominent figure in the medical physics community. Since its founding, the company has continually strived to be a good corporate and environmental citizen. Building upon its past, and its founders' beliefs, Standard Imaging has merged many of its development, manufacturing, workplace safety, facility and quality activities with its environmental concerns and goals. This resulted in the company implementing a comprehensive environmental management system (EMS). This system was formally launched, with governing operating procedures, goals and metrics, in 2008.

From its facility in Middleton, WI, Standard Imaging is committed to designing, manufacturing and commercially distributing a variety of instruments aimed at radiation calibration and quality assurance for health care. The majority of the products support the radiation treatment of cancer and cardiovascular disease, radiosurgery, diagnostic radiology, medical imaging and biomedical equipment calibration. Specifically, the products focus on high dose (HDR), low dose (LDR) and intravascular (IVB) brachytherapy (invasive radioactive seed-based therapy), and external beam radiation therapy. Recently released products address the needs of tomotherapy, rotational therapy, intensity modulated radiation therapy (IMRT), and image guided radiation therapy (IGRT) through a leveraging of current technologies.

Executive Summary

For Standard Imaging, 2014 was the 5th complete year under the WI DNR Green Tier I Certification program, although it was the 7th year since the implementation of the EMS. As far as Standard Imaging can determine, it appears that it was the first medical device company in the program. The EMS is now fully integrated and functional under the umbrella of the quality management system (QMS). The year was again a success with many significant gains, including:

- The receipt of additional awards for the company that highlighted among its many achievements, the EMS efforts.
- Active involvement with the WI DNR aimed at advancing the Green Tier program.
- Positive EMS periodic metric trends.
- Continued refinement of the EMS requirements with the QMS.
- Continued implementation of paperless UW-ADCL calibration records.
- Continued dominant use of local and state suppliers.
- Continued focus on eliminating DEHP and BPA from products.
- Continued immeasurable employee radiation exposure.
- Continued solar generated electricity covering nearly 10% of the needs of the company.
- Continued operation of the paper and metal waste product recycling process.
- Completion of RoHS2 compliance efforts for the EU.
- The successful completion of the internal and external audit to EMS related requirements and the ISO 14001 standard.

The company was also the recipient of more prestigious awards in which its EMS efforts were a factor in achieving the award. It should also be noted that the company has won two major environmentally focused awards in the past few years. The awards received in 2014 were the following:

Presenter	Year	Award
	2014	Wisconsin Small Business Innovation Consortium, Small Business Innovation Award for Outstanding Achievement
	2014	Madison College Certificate of Recognition Celebrating WI Manufacturing – QA BeamChecker Plus
	2014	<u>In Business</u> Made in Dane 25 – Exradin W1 Scintillator



Environmental Performance

The EMS performance can best be presented through the periodic metrics presented to the management team of Standard Imaging. The company chooses the metric categories annually during the first management team meeting of the new year. The metrics for 2014 were:

Environmental Efforts	FY14 Ave	FY13 Ave	12 Mon Trend
Finger Radiation Exposure per Bunker User	<1.0 mRem	<1.0 mRem	—
Products Containing DEHP >0.1% w/w	3	3	—
Patient Contact Products Containing BPA	0	0	—
Printer/Copy Paper Cases Ordered	6	6	—
Printer/Copy Paper Ordered / Employee	0.09	0.09	—
Paperless UW-ADCL Calibration Reports	528	449	▲
Electricity Generated by Solar Panels	5016 kwh	3954 kwh	▲
Coal Saved by Solar Panels (~1.0 lbs / kwh)	5,016 lbs	3,954 lbs	▲
CO2 Saved by Solar Panels (~2.2 lbs / kwh)	11,035 lbs	8,699 lbs	▲
Suppliers in Dane Co./WI	31% / 60%	31% / 59%	—
Total Electricity Used	102,154 kwh	107,010 kwh	▼
Total Electricity Used/Employee	1548 kwh	1647kwh	▼
Total Water Used	34.6 kgal	32.8 kgal	▲
Total Water Used/Employee	524 gal	497 gal	▲

Not reflected in the current metrics, efforts continued at Standard Imaging to develop products that are quite frugal with regards to energy consumption. This has led to products typically powered by a standard 120 Vac to 9 Vdc wall-brick transformer drawing a maximum of only about 1.2 Amps when in use. The real energy savings come from the reduced radiation treatment system set-up and run times for patient treatment planning and required periodic quality assurance tests. Since most radiation treatment systems incorporate a linear accelerator, they are enormous consumers of electrical power. Thus, any reduction in run times directly corresponds to energy savings, as well as greater throughput which allows for the treatment of more patients.

The company also complies with the European Union (EU) WEEE (Waste Electrical and Electronic Equipment) directive regarding the recycling and disposal of electrical and electronic equipment and is now complete in complying with the updated EU RoHS2 (Restriction of Hazardous Substances) directive addressing the design of electrical and electronic equipment. With regards to transportation, Standard Imaging is located on a major bus line which is often used by employees. It also encourages riding a bike to work and on a typical summer day, will have more than 10% of its employees choosing this method of transportation. In support of biking, the company provides indoor bike racks to facilitate this means of transportation.



EMS Audit Result Summary

In late 2010, the first external EMS audit of Standard Imaging against the ISO 14001 standard was completed by an ISO certified lead auditor who was also a RAC professional. From the audit and the many subsequent ones, it is evident the EMS is effective for the company, as all have been successfully passed. Below are the relevant audits completed in 2014.

Date	Audits / Inspections
06/04/14	Standard Imaging Internal QMS / EMS Audit
08/05-07/14	Intertek ISO 9001 / 13485 / EU CE-MDD Surveillance Audit
12/09-11/14	ANVISA (Brazil) QMS / EMS Audit
12/16/14	Supplier QMS / EMS Audit

Economic Performance

For a heavily regulated company like Standard Imaging, it is difficult to determine a precise economic impact for many of its EMS efforts. Some, such as the solar generated electricity have positive and measurable impact that is reflected monthly, however most others are more indirect. For example, using local or state suppliers significantly reduces transportation costs, but quantifying the exact savings is difficult and time consuming. Additionally, safely guarding users from DEHP and BPA, or employees from radiation exposure provides significant healthcare and regulatory compliance savings, but again is tough to quantify. Probably more important is that Standard Imaging continues to be a financially successful and growing company with a strong EMS program, demonstrating that being a good environmental corporate citizen does not conflict with being a successful company.

Stakeholder Involvement

With its EMS program under the umbrella of its regulated QMS program, stakeholder involvement is mandated. Training and metrics are integral to its ongoing operation and success. Periodic metrics are placed on the company intranet viewable by all employees. Additionally, all employees are eventually part of the internal QMS and EMS annual audits, providing visibility to the programs and their objectives. Lastly, Standard Imaging continues to be involved with the City of Middleton and Sustain Dane of Dane County regarding their environmental efforts.

WI DNR Relationship

Standard Imaging enjoys a healthy relationship with the WI DNR and its Green Tier Staff. This staff is readily available as a consulting resource. It was active in many meetings with WI DNR regarding advancing the program. Furthermore, participation in the program has helped provide more focus, guidance and efficiency to its EMS efforts. Standard Imaging hopes that it can continue to participate in WI DNR Green Tier meetings as a ways of sharing its lessons learned.

Conclusion

Standard Imaging recommends that other firms join the Green Tier program and reap its benefits!