MIOSHA Radiation Safety Section Inspection Authority Related to XRF Devices and Regulation

General Background

- X-Ray fluorescence spectroscopy (XRF) is a non-destructive analytical technique used to determine the elemental composition of materials.

- XRF machines work by measuring the fluorescent (secondary) x-rays emitted from a sample when exposed to the primary x-ray source. Each element present in a sample produces a set of characteristic fluorescent X-rays. Characteristic x-rays are distinct for each element and allow for quantitative and qualitative measurements.

- The overall purpose of the radiation safety rules is to reduce exposure to unnecessary ionizing radiation. The rules include specific requirements for registration, machine performance standards, operator requirements, and use of dosimetry to monitor exposure to operators.

XRF Machines Registration Requirements

- XRF machines registered with an authorized use of “Analytic” fall under Part 13 of the Ionizing Radiation Rules Governing the Use of Radiation Machines as well as Parts 1-4. All registrants must comply with Parts 1-4.

- Part 13 - Miscellaneous Sources, includes specific requirements for open-beam analytic devices. A common non-compliant condition is the lack of personnel monitoring either by ring or wrist dosimeters to determine the operator's exposure (Rule 487).

  The registrant of any x-ray device must designate a Radiation Protection Supervisor (RPS) to be responsible for radiation protection. This individual is to ensure that operators are trained in the use of the x-ray machines, have basic knowledge of x-ray production, understand the proper use of individual monitoring devices and are familiar with the registrant’s safety procedures and all other applicable rules governing the use of the radiation machine. (NOTE: The RPS has other duties – training and dosimetry are the main responsibilities).

- MIOSHA’s registration of a device is not an approval of any particular activity.

Registration Penalties

- While there are provisions in Part 1 that provide for enforcement which include civil penalties, the Radiation Safety Section (RSS) generally does not issue civil penalties for items of noncompliance. More commonly, RSS will conduct a reinspection with an assessment of a reinspection fee for a continued failure to comply with the rules.

Radiation Safety Requirements for Devices Used on Humans

- All facilities that utilize radiation machines need to comply with Parts 1-4 of the administrative rules. These rules set requirements for things like registration, submission of shielding plans, posting and notification requirements, and they list standards for protection that sets dose limits for workers and members of the public.

- The administrative rules have separate Parts for machines used in medicine, dentistry, and for the specific uses of mammography and computed tomography. In general, these machine standards echo requirements set by the Federal Performance Standards for Radiation machines published by the Food and Drug Administration. The FDA puts requirements on manufactures that produce medical devices. Michigan's administrative rules in general require facilities to maintain equipment to the manufacturer's standard.

- Regarding the intentional exposure of humans, Rule 55(1) states:

    - (1) Nothing in these rules shall be construed as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis, medical therapy, or medical research conducted by a health practitioner licensed under article 15 of the act, MCL 333.1101 to 333.25211; and

    - (2) Intentional exposure of individuals to radiation for diagnostic or therapeutic purposes shall be limited to supervision or prescriptions by a person licensed under article 15 of the act to provide such.

Dose Requirements

- Rule 60(1) requires that registrants conduct operations such that the dose to an individual member of the public does not exceed a dose equivalent of 1 mSv per year. The dose equivalent is a dose to a point (i.e., location of interest) on the body. If a registrant exposes individuals to doses greater than this level, the rules require the exposure to be conducted under the supervision or prescription of a licensed physician.

- Once under the supervision of a physician, the rules do not impose any limit on the dose. It is then the physician's responsibility to evaluate the risk versus benefit for the application of radiation to humans above the 1 mSv dose equivalent level. Doses well in excess of the 1 mSv dose equivalent level are commonly administered under the supervision of a physician for a variety of purposes.

- The radiation safety rules are not designed to establish dose limits that are "safe" or "unsafe" for human exposure, and the 1 mSv dose equivalent limit in Rule 60 is not meant to establish a "safe" versus "unsafe" line of demarcation. Instead, it is a level where, if exceeded, the exposure to the individual should be evaluated by a physician to ensure the dose is medically appropriate. Generally speaking, exposure to ionizing radiation of greater than 1 mSv does not mean the person is at risk of harm.