ENVIRONMENT, HEALTH & SAFETY

ALARA Program

Guideline

Issue Date: Pre-1987 Revision Date: 10/09/19

Applies To: Employees and members of the public exposed to ionizing radiation from licensed activities.

Regulatory Position

Each licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA). [10 CFR 20.1101(b)]

Licensees must develop, implement, and maintain procedures for protective measures to be taken by radiation workers to maintain their occupational doses ALARA. [NUREG-1556, Vol. 9, Rev. 2]

Purpose

The purpose of the ALARA Program is to maintain exposures to radiation as far below the regulatory limits as practical with consideration of economics, the state of technology, and other societal considerations. To be effective, the ALARA Program must have established standards of practice and procedures which are accepted and supported by University of Michigan (U-M) management, the Radiation Policy Committee (RPC), and personnel involved in the use of radioactive material or radiation-producing machines.

Implementation of the ALARA Program is the responsibility of the U-M Radiation Safety Service (RSS), Environment, Health & Safety (EHS), and is overseen by the RPC.

Definitions

ALARA: acronym for "as low as (is) reasonably achievable," which means making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to state of technology, the economic of improvements to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Collective dose: the sum of the individual doses received in a given period by a specified population from exposure to a specified source of radiation.

Member of the public: any individual except when that individual is receiving an occupational dose.

Occupational dose: the internal and external dose of ionizing radiation received by workers in the course of employment in which the individual's assigned duties involved exposure to sources of radiation,

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whether in possession of the licensee/registrant or other person. Does not include the dose received from natural background sources, doses received as a medical patient or participant in medical research programs, or "second-hand doses" received through exposure to individuals treated with radioactive materials.

Public dose: dose received by a member of the public from exposure to a radiation machine under the control of the registrant (or to radioactive material released by the licensee, or to any other source of radiation under the control of a licensee). Does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released under NRC regulation (10 CFR 35.75), or from voluntary participation in medical research programs.

U-M management: the entities that oversee and support implementation of the radiation safety program on behalf of the Regents and the U-M President. For the purposes of the radiation safety program, U-M management is represented by the Associate Vice President for Facilities and Operations, who is knowledgeable about the radiation safety program, actively participates as a member of the RPC, and has the authority to delegate resources to the radiation safety program.

Responsibilities

- On behalf of the Board of Regents, as the licensee for radioactive material use and the registrant of radiation-producing machines, U-M management (through the RPC) is committed to the program described herein for keeping doses to radiation workers (individual and collective) and members of the public "as low as reasonably achievable" (ALARA). In accordance with this commitment, U-M hereby describes an administrative organization for radiation safety and will continue to develop the necessary policies, procedures, and instructions to foster the ALARA concept within the institution. The radiation safety program will include the RPC, the Radiation Safety Officer (RSO), and the Radiation Safety Service (RSS) staff.
- The RSO and/or RPC will perform a formal annual review of the radiation safety program, including ALARA considerations.
- Modifications to operating and maintenance procedures and to equipment and facilities will be implemented to reduce occupational and public doses unless the cost is considered to be unjustified by the collective or individual reduction in dose, in the judgement of U-M management, the RSO, and/or the RPC.
- In addition to maintaining occupational doses as far below regulatory limits as is reasonably achievable, the sum of the radiation doses received by occupationally exposed individuals and by members of the public will also be maintained ALARA. It would not be desirable, for example, to hold the highest individual doses to some fraction of the applicable limit if this involved exposing additional individuals and significantly increasing the sum of radiation doses received by all exposed personnel, when other reasonable alternatives do not exist that may be effective in keeping both individual and collective doses low.
- The RPC will be familiar with pertinent Federal and State agency regulations, safety procedures for work involving sources of ionizing radiation, the U-M's NRC material licenses, and license amendments. The RPC and RSS staff will review the training and experience of proposed radioactive material users to determine that their qualifications are sufficient to enable the individuals to

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perform their duties and are in accordance with pertinent regulations and conditions of the appropriate license.

- New uses of radioactive material will be reviewed by the RPC, RSO, and RSS staff to ensure that occupational and public radiation doses will be maintained ALARA. RSS will monitor uses of radiation-producing machines and work with users to maintain occupational and public doses ALARA.
- The RPC or RSO will review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all new requests for authorization to use radioactive material at the U-M.
- The RPC, RSO, or RSS staff will prescribe special conditions to users of radioactive materials, such as requirements for bioassays and special survey or monitoring procedures, as necessary.
- The RPC will review quarterly the RSO's summary report of the occupational radiation dose records of all personnel, giving special attention to individuals or groups of radiation workers whose occupational radiation doses appear unusual or excessive.
- The RPC and RSO will establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials or radiation-producing machines are used are appropriately instructed as required by regulation.
- The RPC will annually review the RSO's summary report of the entire radiation safety program to confirm that all activities are being conducted as safely as possible, in accordance with applicable regulations and the conditions of the U-M's NRC licenses, and consistent with the ALARA program.
- The RPC or RSO will recommend remedial action to correct any deficiencies identified in the radiation safety program.
- The RSS staff will implement ALARA through the following measures:
 - Consider ALARA when reviewing and/or approving proposed uses of radioactive materials or radiation-producing machines, and recommend modifications when necessary.
 - Formulate written procedures where applicable for specific tasks.
 - Monitor and track activities which affect potential occupational and public doses.
 - Provide the training and guidance necessary to users of radiation-producing machines, personnel exposed to radiation-producing machines, users of radioactive material, Authorized Users, U-M management, the RPC, and other U-M personnel (as necessary) to meet the goals of the ALARA program.
 - Review records of radiation surveys, occupational doses, and environmental releases at least annually to determine compliance with ALARA goals and good radiological safety practices.

Delegation of Authority

- U-M management and the RPC will delegate authority to the RSO for the enforcement of the ALARA program and concept.
- The RPC will support the RSO when it is necessary for the RSO to assert authority. If the RPC overrules the RSO for any reason, the basis for the RPC action will be recorded in the minutes of the quarterly RPC meeting.
- The RSO has the authority to immediately halt any activity that is considered to be a threat to health and safety or a violation of the conditions of a U-M's NRC materials license or regulatory agency regulations. The RSO and RSS staff have the authority to inspect any area or facility at the U-M

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where sources of ionizing radiation are used or stored. This authority is granted to the RSO by the NRC license, U-M management, and the RPC.

Review of the ALARA Program

- The RPC, RSO, and RSS staff will encourage all users of radioactive materials or radiation-producing equipment to review current procedures and develop procedures as appropriate to implement the ALARA concept.
- The RSO will perform a quarterly review of occupational radiation doses and doses to members of the public with special attention to instances in which the ALARA II investigation levels specified in Tables 1.0 and 2.0 are exceeded. The results of these quarterly reviews will be presented to the RPC during routine quarterly RPC meetings. The principal purpose of this review is to assess trends in occupational doses and doses to members of the public as an index of the ALARA program quality and to decide if action is warranted when investigation levels are exceeded.
- The RPC will evaluate the U-M's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, RSS staff, Authorized Users (or supervisors), and radiation workers.

TABLE 1.0: ALARA Investigation Levels for Occupational Exposure

[mrem, year-to-date]

	ALARA I	ALARA II
Deep dose equivalent [DDE] or effective dose equivalent [EDE]*	500 (10%)	1,500 (30%)
Lens dose equivalent [LDE]	1,500 (10%)	4,500 (30%)
Skin dose equivalent (SDE)	5,000 (10%)	15,000 (30%)
Extremity dose equivalent (SDE)	25,000 (50%)	37,500 (75%)
Internal (EDE, based on applicable Allowable Limit on Intake [ALI])	500 (10%)	1,500 (30%)

Percentage of applicable regulatory limits; 100 mrem = 1 mSv

* EDE calculation based on Michigan *Ionizing Radiation Rules*, Rule 57(3)(b)

TABLE 2.0: ALARA Investigation Levels

[Quarterly Effluent / Environmental Releases] [% of 10 CFR Part 20 - Appendix B, averaged over calendar quarter]

All radionuclides 20% 50%	

Radiation Safety Officer

• Annual and Quarterly Reviews

REVIEW	THE RSS STAFF AND/OR RSO WILL
Annual Review of the Radiation Safety Program	 Perform an annual review of the radiation safety program in accordance with 10 CFR 20.1101 and include a review of occupational doses based on ALARA concepts. As needed, review specific methods of use on a more frequent basis.
Quarterly Review of Occupational Exposures	 Perform reviews of occupational doses, not less than once per calendar quarter. Review radiation worker doses to confirm that they are ALARA in accordance with this ALARA Program. Prepare an occupational radiation dose summary report each quarter for the RPC.
Quarterly Review of Radiation Survey Records	 Review radiation incidents and surveys in unrestricted and restricted areas to determine that dose rates and contamination levels were at acceptable levels during the previous quarter. Prepare quarterly summary report of all incidents for the RPC.
Annual Review of Airborne Effluents	 Review airborne effluent releases to confirm that radionuclide concentrations released to the environment are ALARA. Prepare an annual summary report of effluent releases for the RPC.

- Educational Responsibilities of the ALARA Program
 - The RSO and RSS staff will inform radiation workers about the ALARA program efforts during routine or special in-house training sessions, training literature, and/or online training.
 - The RSO and RSS staff will ensure that Authorized Users, clinical and research personnel, and ancillary personnel who may receive in a year an occupational radiation dose in excess of 100 mrem will be instructed in the ALARA philosophy and informed that U-M management, the RPC, the RSO, and the RSS staff are committed to implementing the ALARA program.
 - The RSO or RSS staff will inform female radiation workers of their right to voluntarily declare a pregnancy, the dose limits that will be applied, that additional exposure monitoring will be provided, and that work restrictions may be imposed, depending on the type of work performed. See "Individuals Who Receive Occupational Radiation Doses," next page.
- Cooperative Efforts for Development of ALARA Procedures
 - The RSO or RSS staff will assess users of radioactive material and radiation-producing machines for acceptable ALARA practices.
 - The RSO and RSS staff will encourage suggestions from radiation workers for improving radiological safety practices and complying with regulatory requirements.
- Reviewing Instances of Deviation from Good ALARA Practices
 - The RSO or RSS staff will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO or RSS staff may implement changes in the program to maintain doses ALARA.

Authorized Users of Radioactive Material

- New Methods of Use Involving Potential Radiation Doses
 - When applicable, Authorized Users should consult with the RSO or RSS staff regarding radiological safety issues during the planning or pre-authorization stage before using radioactive materials for new uses.
 - Authorized Users should review each planned use of radioactive material and consider the implementation of ALARA-based techniques during radioactive material work. Trial runs of new uses will be encouraged by the RSS staff.
- Authorized User's Responsibility to Supervise Individuals
 - Authorized Users and/or RSS should explain the ALARA concept and the need to maintain exposures ALARA to all supervised clinical and research personnel.
 - Authorized Users and/or RSS should ensure that pregnant radiation workers and female radiation workers of childbearing age are informed of the ALARA concept as it pertains to pregnant employees.
 - Authorized Users should ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good radiological safety practices and in maintaining exposures ALARA.

Individuals Who Receive Occupational Radiation Doses

- Radiation workers will be instructed in the ALARA concept and its relationship to research and clinical work and working conditions, and will complete retraining annually.
- Employees who become pregnant may voluntarily inform RSS in writing of their pregnancy, in order to monitor doses to the embryo/fetus and ensure they remain within applicable regulatory limits (500 mrem per gestation period and 50 mrem per month).

Establishment of Investigation Levels for Radiation Exposures

Investigation levels have been established for occupational radiation doses and doses to members of the public which, when exceeded, will initiate a review or investigation by the RPC, RSO, and/or RSS staff. The investigation levels are listed in Table 1.0 and Table 2.0. These levels apply to occupational exposures.

Occupational Radiation Dose Monitoring

The RSS staff and/or RSO will review the results of occupational radiation dose monitoring not less than once in any calendar quarter and report doses (to the RPC) that exceed ALARA Levels I and II. RSS will take the following actions at the ALARA investigation levels listed in Table 1.0 and Table 2.0:

- Occupational Exposures < ALARA Level I
 - No RSS action and no response required unless deemed necessary by the RSS staff and/or RSO.
- Occupational Exposures ≥ ALARA Level I but < ALARA Level II
 - Written notification regarding the cumulative (year-to-date) dose will be sent, along with information about reducing occupational dose.
 - No response required unless deemed appropriate by the RSS staff and/or RSO.

- Occupational Exposures ≥ ALARA Level II
 - Written notification regarding the cumulative (year-to-date) dose will be sent, along with information about reducing occupational dose.
 - The RSS staff and/or RSO may investigate the potential causes of occupational doses meeting or exceeding ALARA Level II and, if warranted, recommend appropriate radiological safety procedures to reduce the probability of recurring elevated exposures.
- RSS staff will forward copies of written notifications (and may forward copies of documented investigations) to:
 - Exposed individual
 - Supervisor or Authorized User
 - RSS dosimetry file

Chronic Individual or Departmental Exposures > ALARA Level II

RPC and/or RSO may establish a review committee to investigate chronic occupational radiation doses exceeding ALARA II levels, review experimental and radiological safety procedures, and recommend remedial ALARA measures/action if necessary to reduce future occupational doses.

The review committee may consider establishing a new, higher investigation level for an individual or group whose exposures consistently exceed ALARA Level II. Justification for revised investigation levels must be approved by the RPC, documented in the RPC minutes for NRC review, and consistent with good ALARA practices.

Establishment of Investigation Levels for Airborne Effluent Releases

The RSS staff and/or the RSO will annually review the results of effluent monitoring and take the following actions at the ALARA investigation level:

Written notification regarding an elevated radionuclide release \geq 50% of the NRC effluent release limit for a specific sampling period and written notification and a health physicist investigation for effluent releases \geq 50% of NRC limits over a specific calendar year.

References

Michigan Department of Licensing and Regulatory Affairs, Ionizing Radiation Rules Governing the Use of Radiation Machines (May 2016).

U.S. Nuclear Regulatory Commission, Title 10, Code of Federal Regulations, Part 20 - Standards for Protection Against Radiation.

U.S. Nuclear Regulatory Commission, Regulatory Guide 8.10 (Revision 2), "Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Reasonably Achievable" (August 2016).

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.20 (Revision 1), "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors" (April 2012).

University of Michigan, "Radiation Policy Committee Charge" (March 1996)

Original	Pre-1987 (JDJ)
Revisions:	March 1991 (MLD)
	December 1994 (MLD)
	March 1995 (MLD)
	August 2017 (KWF/AKJ)
	December 2018 (KWF/MLD/DAP)
	October 2019 (KWF)