The Administrative Procedure Act requires the publication of substantive policy statement currently in use, including its full text, if practicable. (A.R.S. § 41-1091.01). Substantive policy statements are written expressions which inform the general public of an agency's current approach to rule or regulation practice. This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona administrative procedure act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under section 41-1033, Arizona Revised Statutes, for a review of the statement.

NOTICE OF SUBSTANTIVE POLICY STATEMENT

ARIZONA RADIATION REGULATORY AGENCY

[ARRA-REG-8.37]

1. **Subject of the substantive policy statement and the substantive policy statement number by which the policy statement is referenced:**
   ALARA Levels for Exposures and Effluents from Radiation Sources

2. **Date the substantive policy statement was issued and the effective date of the policy statement if different from the issuance date:**
   Effective September 1994

3. **Summary of the contents of the substantive policy statement:**
   Provides information on designing an acceptable ALARA program.

4. **A statement as to whether the substantive policy is a new statement or a revision:**
   This is a current policy statement.

5. **The agency contact person who can answer questions about this substantive policy statement:**

   Name: Brian D. Goretzki, Interim Director

   Address: Arizona Radiation Regulatory Agency
   4814 South 40th Street
   Phoenix, AZ 85040

   Telephone: (602) 255-4840

11-30-16

APPROVED BY (DIRECTOR) DATE

Policy Number: ARRA-REG-8.37
Effective Date: September 1994

Subject Title: ALARA Levels for Exposures and Effluents from Radiation Sources

A. INTRODUCTION

Section A.A.C. R12-1-416.G. of Article 4, Standards for Protection Against Radiation," requires that each licensee and registrant ensure that:

> "Each licensee or registrant shall show compliance with the annual dose limit listed above (A.A.C. R12-1-416.A.) by:
>
> 1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
>
> 2. Demonstrating that:
>
> a. The annual average concentrations of radioactive material released in the gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and
>
> b. If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year."

In addition, A.A.C. R12-1-407.B. requires that:

> "The licensee or registrant shall use to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational and public doses that are as low as reasonably achievable (ALARA).

This regulatory guide provides guidance on designing an acceptable program for establishing and maintaining ALARA levels exposures from sources of ionizing radiation and for gaseous and liquid effluents at radioactive materials facilities. Radioactive material facilities are those facilities at which the possession or use of radioactive material is licensed pursuant to Article 3 of this Chapter.

Additional guidance on ALARA programs can be found in other regulatory guides. While these guides deal primarily with occupational exposure and may be specific to one type of license, they contain programmatic information that may be useful to all licensees. They are as follows:

• Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable." This guide delineates the components of an ALARA program.

• Regulatory Guide 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will be As Low As Reasonably Achievable."

B. DISCUSSION

At the relatively low levels of radiation exposure in the United States and Arizona, it is difficult to demonstrate a relation between exposure and any health effects. The dose limits in Article 4 are based on limiting the dose to what is considered to be an acceptable level of risk to the exposed individual. Still, any radiation exposure may carry some risk. Thus, the Agency requires licensees and registrants to take actions, to the extent practicable, utilizing procedures and engineering controls to further reduce risk below the levels implicit in the dose limits in keeping with the principle that exposures should be as low as reasonably achievable. This is the goal and purpose for radiation protection programs. In order to achieve this goal, licensees must control the way radioactive material is handled from receipt through disposal.

Agency licensees and registrants have traditionally reduced exposures and effluents to small fractions of the dose limits using the ALARA process. Recently, the Environmental Protection Agency (EPA) conducted 2 nationwide studies of radioactive materials facilities. The first was a survey of 367 randomly selected nuclear material facilities. The highest estimated dose to a member of the public from effluents was 8 mrem/yr, based on very conservative modeling. In addition, 98 % of the facilities examined had doses to members of the public resulting from effluents less than 1 mrem/yr. The second study evaluated effluent from 43 additional facilities that were selected because of there potential for effluent releases resulting in significant public. exposures. Of these, one exceed 10 mrem/yr. to a member of the public. Based on this information, and the on going Agency program of licensing, registering, and inspection, the Agency expects that the goals suggested in this guide will be easily achievable by all Agency licensees and registrants.

The Agency staff will be examining licensee and registrant programs to determine compliance with the requirements of Article 4. In the event that a particular facility licensee or registrant establishes ALARA goals that are less stringent than the goals identified in this guide, or consistently fails to achieve ALARA goals it has established pursuant to this guide, the Agency staff will conduct a more detailed review of that program to determine the rationale for the greater levels. In such circumstances, the Agency will evaluate the rationale provided by the licensee or registrant, as well as the license's or registrant's operations, to determine whether the licensee or registrant has established an adequate ALARA program and is operating that program in compliance with A.A.C. R12-1-407.B.

This guide deals with only a part of a licensee's or registrant's overall radiation protection program. Specifically, it deals with the application of ALARA in controlling gaseous and liquid effluents. In addition to controlling doses resulting from the release of effluents, licensees and registrants must implement a radiation protection program that controls dose rates in unrestricted areas to maintain overall doses to workers and members of the public ALARA and below the limits in Article 4. Licensees or registrants may choose to focus their evaluation of public dose to members of a critical group as suggested by the International Commission on Radiological

Protection (ICRP) as a means of identifying and controlling the exposure to the individual member of the public likely to receive the highest exposure.

Agency licensees and registrants have taken actions to maintain doses to both workers and members of the public ALARA under the admonition contained in prior versions of Article 4, which required licensees and registrants "make every reasonable effort" to maintain doses and effluents ALARA. Agency licensees and registrants have generally reduced doses to relatively small fractions of the dose limits. Therefore, the Agency staff does not expect that most licensees or registrants will need to max, significant changes to procedures, operations, and equipment in order to be in compliance with the requirements of R12-1-407.B. However, for those licensees or registrants who have not previously developed a radiation protection program that includes written procedures and policies as well as a commitment to ALARA, additional steps may be necessary to demonstrate

Compliance with requirements now explicit in Article 4 to maintain doses ALARA.

Components of an effective radiation protection program as required by A.A.C. R12-1-407.B., include radiation exposure control, written procedures and policies, control of radioactive materials, radioactive contamination control, radioactive waste management, training, program reviews, and audits. Guidance on other facets of a radiation protection program for facilities is currently under development.

C. REGULATORY POSITION

An ALARA program for effluent control to control doses to members of the public should contain the following program

elements:

1. Management commitment to ALARA, including goals,

2. Procedures, engineering controls, and process controls,

3. Surveys and effluent monitoring,

4. ALARA reviews, and

5. Worker training.

These program elements, while given specifically for effluents in this guide, are also applicable to the control of direct exposure.

MANAGEMENT COMMITMENT TO ALARA, INCLUDING GOALS

The single most critical aspect of successfully achieving ALARA in the radiation safety program is the commitment of Management to maintain doses ALARA, both occupational and to the public. The licensee's or registrant's radiation protection program (including ALARA elements) should be commensurate with the potential hazards associated with the activity.

1.1 ALARA Policy

The licensee or registrant should establish an ALARA policy that is issued and supported by the highest level of management. All employees should be made aware of the ALARA policy through training. This policy should make clear that all personnel will be responsible for ensuring that work they perform is in accordance with ALARA procedures.

1.2 ALARA Goals

To assist in demonstrating compliance with the requirements of Article 4, the licensee or registrant should set ALARA goals for effluents at a modest fraction of the values in Appendix B., Table 2 Columns 1 and 2. These goals may be set independently for gaseous and liquid effluents. Past experience and effluent information reported to the Agency staff indicate that goals within a range of 10to 20% of Appendix B values or less can be achieved by almost all facilities. However, establishing a goal is not intended as setting a precedent or a de facto limit. Goals may need to be adjusted up or down on the basis of the annual review of what may be ALARA for the particular circumstance.

If the licensee or registrant chooses to demonstrate compliance with R12-1-407 through a calculation of the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose, the licensee or registrant should set the ALARA goal modest fraction of the dose limit for members of the public. Experience indicates that values of about 0.1 mSv/yr (10 mrems/yr) or less should be practicable for almost all facilities. Licensee and registrants need not assume worst case models when calculating doses but rather should make assumptions that will result in realistic estimates of actual doses receives by the member of the public likely to receive the highest dose.

If the circumstances of a particular case are such that the licensee or registrant cannot achieve effluent concentration less than 20% of the Appendix B values or demonstrate by calculation that the TEDE to the individual likely to receive the highest dose is less than 0.1 mSv/yr (10 mrem/yr), The ALARA philosophy continues to apply, and the license should demonstrate compliance with the requirements of A.A.C. R12-1-407.B. by evaluating procedures, engineering controls, and process control is as described in Regulatory Position 2. below.

1.3 Investigation Levels

In addition to ALARA goals, the licensee or registrant should establish investigation levels at effluent values that are close to normal or anticipated release levels. If exceeded, an investigation should be initiated and corrective actions should be taken, as appropriate.

1.4 Radiation Safety Committee, Radiation Safety Officer

For licensees that have a radiation safety committee, one responsibility of that committee should be to establish ALARA goals. The committee must meet at least annually to review the radiation protection program content as required in the licensee's approved procedures. The committee should also review ALARA goals and discuss ways to further reduce doses if necessary and appropriate. Goals may need to be adjusted on the basis of the committee's review. The

committee should assess short-term and long-term performance in terms of achieving ALARA goals. ALARA goals and results should be reported at least annually to senior management with recommendations for changes in procedures or equipment needed to accomplish the requirements.

For licensee with no radiation safety committee or registrants, the radiation safety officer should be responsible for setting, adjusting, and periodically reviewing the radiation protection program and the ALARA goals.

2. PROCEDURES, ENGINEERING CONTROLS, QUALITY CONTROLS, AND PROCESS CONTROLS

Licensees and registrants should consider available engineering options to control the release of effluents and exposures to unrestricted areas and to the occupational environment. Examples of the available options include shielding, filtration, encapsulation, adsorption, containment, development techniques, grid selection, timer consistency, and storage of wastes for decay. If further reduction in effluents or exposures are needed to achieve ALARA goals, the recycling or process fluids; leakage reduction; modification to facilities, operations, or procedures; collimation; tube head leakage; or reducing the number of retakes due to improper positioning should be considered. These should be implemented unless an analysis indicates that a substantial reduction in collective dose would not result or costs are considered unreasonable. A determination of reasonableness may be based on a qualitative analysis requiring the exercise of judgement and consideration of factors that may be difficult to quantify. These factors could include nonradiological social or environmental impacts, the availability and the practically of alternative technologies, and the potential for unnecessarily increasing occupational exposures.

Alternatively, reasonableness may be based on a quantitative cost benefit analysis. Preparation of an ALARA cost benefit analysis requires the use of a dollar value per unit dose averted. The U.S. Nuclear Regulatory Commission and the Agency accept $1,000 per person-cSv (man-rem) and may be used for such analysis. The Agency is aware that various other methodological approaches may be used in justifying a dollar value and will consider other values. These requests will need to be well justified and supported for acceptance.

3. SURVEYS AND EFFLUENT MONITORING

Licensees and registrants must perform surveys and monitoring sufficient to demonstrate compliance with the requirements of A.A.C. R12-1-416. This includes the monitoring and surveys that may be necessary to determine whether radiation levels and effluents meet the licensee's or registrant's established ALARA goals. These surveys should include dose rates in unrestricted areas, as well as air and liquid effluent monitoring, as appropriate.

3.1 Surveys for Sources of Radiation

The licensee or registrant should evaluate the exposure in unrestricted areas for each source of radiation. This evaluation shall include an instrument measurement if appropriate. The licensee or registrant is to assure that the requirements of A.A. C. R12-1-416 are met. Further, to the extent practicable the radiation exposure is to be reduced below this limit to the ALARA goal

determined by the licensee or registrant to be appropriate for the facility. The facility through the radiation safety officer should document this evaluation and the appropriateness of the ALARA goals.

3.2 Airborne Radioactive Effluent Monitoring

When practicable, releases of airborne radioactive material effluents should be from monitored release points (e.g., monitored stacks, discharges, vents) to ensure that the magnitude of such effluents is known with a degree of confidence to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure that these monitors provide reliable indications of actual effluents.

A.A.C. R12-1-416.E. requires that releases of airborne radioactive material not exceed 0.1 mSv (10 mrem) per year to any member of the general public as calculated using the U.S. Environmental Protection Agency Airdose calculation method. Copies of this method are available from the Agency.

Effluent monitoring systems should be designed in accordance with ANSI Nl3.1 (1969), " Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities," and ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents." Copies of ANSI standard may be obtained from the American National Standards Institute, Inc., 1430Broadway, New York, NY 10018.

In addition to the U.S. Environmental Protection Agency Airdose calculation methodology, NCRP Commentary No.3, "Screening Techniques for Determining Compliance with Environmental Standards," published in January 1989 and the addendum published in October 1989provide acceptable methods for calculating dose from airborne radioactive materials. Copies may be purchased from the National Council on Radiation Protection and Measurements, NCRP Publications, 7910 Piedmont Ave., Bethesda, MD 20814. Licensees may use such computer codes as long as they can demonstrate that the code uses approved methods appropriate to their situation.

3.3 Liquid Effluent Monitoring

When practicable, releases of liquid radioactive effluents should be monitored. Since the quantities being released must be known prior to release into the sanitary sewers, releases pursuant to A.A.C. R12-1-436.A. do not have to have additional monitoring.

3.4 Unmonitored Effluents

If a licensee has release points for which monitoring is not practicable, the licensee should estimate the magnitude of the Unmonitored effluents. For instance ,a research hospital or university broad scope licensee might have dozens of locations where radioactive material could be released. The licensee should estimate the magnitude of unmonitored releases and include those estimated amounts when demonstrating compliance with the dose limits and the licensee's ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in

these areas or the number of procedures performed or other appropriate methods. When practicable, unmonitored effluents should not exceed 30% of the total estimated effluent releases.

4. ALARA REVIEWS

According to A.A.C. R12-1-407.C., the content and implementation of the radiation protection programs, which would include the ALARA program, must be reviewed annually. This review should include analysis of trends in work load, release concentrations, and radiation source usage as well as other available monitoring data. The review should provide a documented files for determining whether changes are needed in systems or practices to achieve ALARA goals. In addition, the licensee Registrant should review all designs for system installations or modifications to ensure compliance with A.A.C. R12-1-407.B. The results of ALARA reviews should be reported to senior management along with any recommendations for changes in facilities or procedures that are deemed necessary to achieve ALARA goals.

5. WORKER TRAINING

Specific training on ALARA should be provided. as a part of the annual employee radiation protection training (see A.A. C. R12-1-1003). For an ALARA program to be successful, employees must understand the ALARA program's goals and principles. The radiation protection staff should be available to help clarify the ALARA policy and its goals and to assist employees both during training and throughout the year.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants, licensees, and registrants regarding the Agency staff's plans for using this guide.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portion of the Agency's regulations, the methods described in this guide will be used in the evaluation of applications for new facilities, renewals, or amendments, and for determining compliance with Article 4.