

STATE OF MINNESOTA

BEFORE THE MINNESOTA

COUNTY OF HENNEPIN

COMMISSIONER OF HEALTH

In the matter of the adoption of
Rules Relating to the Registration
of Sources of Radiation

STATEMENT OF NEED
AND REASONABLENESS

Amendments to Minnesota Rules, Parts 4730.0500 are being proposed by the Department of Health (MDH) as a revision to the existing rules for sources of radiation.

LEGAL BASIS -

The authority of the Commissioner of Health to adopt the proposed rules derives from several sources. Minn. Stats., Section 144.12, Subd. 1., (1986), imposes the following duties upon the Commissioner of Health:

"**Rules.** The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health. The rules shall not conflict with the charter or ordinance of a city of the first class upon the same subject. The commissioner may control, by rule, by requiring the taking out of licenses or permits, or by other appropriate means, any of the following matters:

...(15) Sources of radiation, and the handling, storage, transportation, use and disposal of radioactive isotopes and fissionable materials; and
...."

The proposed rules come under this authority, since they are intended to aid in the administration of a program which is to protect the public health by reducing the radiation exposure to the operators, employees and the public.

Minn. Stats. Section 144.121 (1986) referring to x-ray machines and facilities using radium specifies that "...The registration shall expire and be renewed as prescribed by the commissioner pursuant to section 144.122." Minn. Stats. Sec. 144.122 (1986) specifies "The state commissioner of health, by rule, may prescribe reasonable procedures and fees for filing with the commissioner as prescribed by statute and for the issuance of original and renewal permits, licenses, registrations and certifications issued under authority of the commissioner...." Both of the above statutes clearly reference the authority of the State Commissioner of Health to develop rules and procedures regarding radiation facilities registered in accordance with Minn. Rules 4730.0100 - 4730.3600.

NEED FOR MDH REVISIONS:

As cited above, MDH has the primary regulatory responsibilities for radiation facilities through the setting of minimum standards applicable throughout the State. The MDH needs to amend the present 4730.0500 and add new subparts 2, 3, and 4 to 4730.0500. These changes will help the Radiation Control program staff to provide better and more efficient service to the 4,000+ registrants, through more timely biennial renewal of registration. Rather than having to experience a paperwork nightmare once every two years, the MDH proposes to

divide the 4,000+ registrants up into eight groups, each of which will be required to renew their registration on successive calendar quarters over a two year period. This will do three things. First, it will smooth out the flow of paperwork over the two years. Secondly, it will eliminate the need for a large mass mailing which is very disruptive of other operations, and spread it over a two year period. Lastly, it will help assure a more prompt response to applicants for renewal and reduce the considerable delay which sometimes occurs under the existing system.

In accordance with Minnesota Statutes, Section 14.10, a notice of intent to solicit outside opinion was published in the State Register at 12 S.R. 1010 on November 9, 1987. Responses and comments received after the announcement was published will be included in the rule making record.

COST OF IMPLEMENTATION TO LOCAL GOVERNMENT:

If the adoption of a rule by an agency will require the expenditure of public moneys by local public bodies, Minn. Stats. Sec. 14.11, Subd. 1, (1986) requires the agency to give a reasonable estimate of the total cost to all local public bodies in the state to implement the rule for the two years immediately following adoption of the rule, if the estimated cost exceeds \$100,000 in either of the two years. The following is the Department's estimate.

There would be no cost to local units of government resulting from the proposed revisions. The current fee schedule is not being changed, only the time when the registration fees are collected. In addition, very few local units of government own sources of radiation which require registration.

SMALL BUSINESS CONSIDERATIONS:

Minnesota Stats., Section 14.115, (1986) requires that an agency consider five factors for reducing the impact of proposed rules on small business. Since many of the radiation registrants are likely to fall within statutory definition of small business, the Department has addressed each of the five factors as presented below.

1. The establishment of less stringent compliance or reporting requirements.

The compliance requirements in the proposed rules are minimally stringent, requiring all radiation registrants to meet minimum requirements. The question of reporting is inapplicable since neither the existing rules nor the proposed amendments to the rules require scheduled reports.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements.

The proposed rules and the existing rules do not require routine reporting. There are no compliance deadlines in the proposed amendments to rules which differ from those in the existing rule.

3. The consolidation or simplification of compliance or reporting requirements.

There are no routine reporting requirements in the proposed amendments to rules.

4. The establishment of design standards for small businesses.

There are no design standards in the proposed amendments to rules.

5. The exemption of small businesses from the rule.

There is no sound public policy rationale by which owners of sources of radiation, some of which are considered small businesses, could be exempted from the proposed amendments. All radiation source registrants regardless of business size, have the potential to overexpose individuals through the use of radiation sources. The health of the operator, employees and the public must be protected. This can only be done through imposition of reasonable rules which necessarily must apply to both small and large businesses if we are to minimize the potential for overexposure to the operator, employees and the public. The proposed amendment does not impose any new responsibilities, but is merely an administrative change to allow for renewal of registration in a more orderly manner.

PROPOSED AMENDMENTS TO MINNESOTA RULES CHAPTER 4730.0500

Existing Minn. Rules Part 4730.0500 is to be amended and new subparts 2, 3, and 4 are to be added.

4730.0500 Subpart 1. This subpart is similar to the existing part 4730.0500 which is being amended by deleting the existing date of the biennial renewal "during the month of January of odd-numbered years". In place of this single day deadline, a schedule showing eight different renewal dates is proposed in new subparts 2 through 4.

4730.0500 Subpart 2. This new subpart specifies the day by which a radiation source registrant must submit the biennial renewal application to the MDH. The renewal deadline is based on where the registrant's business address is located within the state. This schedule was chosen to yield an approximately equal distribution of radiation source registrants from each part of the state in each calendar quarter. The method of sorting county by county was chosen because it would cluster all of the radiation registrants in an area of the state thus facilitating establishment of inspection tours to various parts of the state. Other methods of sorting were considered but none achieved the efficiencies to be realized with the method which has been chosen.

4730.0500 Subpart 3. This new subpart specifies that a radiation registrant will not incur a penalty fee because the source was moved and not renewed with the county of previous location. This subpart was added because up to ten percent of the facilities in the state either move or change ownership every two years. The registrant should not be penalized because the source has been moved. If a registrant were required to renew in the county of previous location, confusion would arise and the efficiencies of the system chosen in the amended rule would soon be lost.

4730.0500 Subpart 4. This new subpart specifies that the staggered biennial renewal takes effect with the 1989-1990 biennial renewal beginning on January 1, 1989. The date was chosen because it was the next scheduled renewal date and would cause the least confusion to the MDH and the registrants. A letter is being sent to all current registrants, explaining how the change is to be implemented and what their legal responsibilities will be as the change is made.

The proposed change is necessary to help MDH speed up the handling of renewals to assure that MDH has in its files the most current information about a particular registrant.

The proposed change is reasonable to the extent that it has virtually no impact on the regulated community while it greatly facilitates the smoothing of the agency's workload and helps assure prompt handling of renewal applications.

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