STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Permanent Rules of the Minnesota Department of Health Relating to Ionizing Radiation, Minnesota Rules parts 4730.1475, 4730.1510, 4730.1655, 4730.1691, 4730.1750, 4730.1950, 4730.2050, and 4730.2150.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Barbara L. Neilson on March 15, 1993, at 9:00 a.m. in the Chesley Room of the Department of Health, 717 Southeast Delaware Street, Minneapolis, Minnesota.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. §§ 14.131 to 14.20 (1992) to hear public comment, determine whether the Minnesota Department of Health (hereinafter referred to as "the Department") has fulfilled all relevant substantive and procedural requirements of law applicable to the adoption of the rules, assess whether the proposed rules are needed and reasonable, and determine whether or not modifications to the rules proposed by the Department after initial publication are substantially different from those originally proposed.

Paul Zerby, Special Assistant Attorney General, 525 Park Street, Suite 500, St. Paul, Minnesota 55103, appeared on behalf of the Department. The Department's hearing panel consisted of Susan McClanahan and June Hart, Radiation Technologists for the Department's Radiation Control Section; Judith Ball, Policy Analyst with the Department's Environmental Health Division; and Larry Souther, Chief of the Department's Radiation Control Section. William Breitenstein of the Department's Radiation Control Section was also present.

Thirty-eight persons attended the hearing. Twenty-eight persons signed the hearing register. Many of the attendees gave testimony about these rules. The Administrative Law Judge received thirty agency exhibits and four public exhibits as evidence during the hearing. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the adoption of these rules.

The record remained open for the submission of written comments until April 5, 1993, twenty calendar days following the date of the hearing. Pursuant to Minn. Stat. § 14.15, subd. 1 (1992), five working days were allowed for the filing of responsive comments. At the close of business on April 12, 1993, the rulemaking record closed for all purposes. The Administrative Law Judge received several written comments from interested

persons during the comment period. The Department submitted written comments responding to matters discussed at the hearings and comments filed during the twenty-day period.

The agency must wait at least five working days before taking any final action on the rules; during that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minn. Stat. § 14.15, subd. 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings of this Report, he will advise the agency of actions which will correct the defects and the agency may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected. However, in those instances where the Chief Administrative Law Judge identifies defects which relate to the issues of need or reasonableness, the agency may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the agency does not elect to adopt the suggested actions, it must submit the proposed rule to the Legislative Commission to Review Administrative Rules for the Commission's advice and comment.

If the agency elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the agency may proceed to adopt the rule and submit it to the Revisor of Statutes for a review of the form. If the agency makes changes in the rule other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, then it shall submit the rule, with the complete record, to the Chief Administrative Law Judge for a review of the changes before adopting it and submitting it to the Revisor of Statutes.

When the agency files the rule with the Secretary of State, it shall give notice on the day of filing to all persons who requested that they be informed of the filing.

Based upon all the testimony, exhibits and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Procedural Requirements

1. On January 13, 1993, the Department filed the following documents with the Chief Administrative Law Judge:

(a) a copy of the rules as proposed for certification by the Revisor of Statutes (Exhibit 2);

(b) an estimate of persons expected to attend the hearing and an estimate of the expected duration of the hearing (Exhibit 1);

(c) the Order for Hearing (Exhibit 3);

(d) the Notice of Hearing proposed to be issued (Exhibit 4);

(e) the Statement of Need and Reasonableness (hereinafter referred to as the "SONAR") (Exhibit 5); and,

(f) a statement that additional discretionary public notice would be given (Exhibit 1).

2. On January 20, 1993, the Department filed a copy of the proposed rules as certified by the Revisor of Statutes.

3. On January 28, 1993, the Department mailed the Notice of Hearing to all persons and associations who had registered their names with the Department for the purpose of receiving such notice. The Department also sent additional discretionary notice to the persons named on the discretionary mailing list.

4. On February 1, 1993, a copy of the proposed rules and the Notice of Hearing were published at 17 State Register 1853.

5. On February 18, 1993, DOH filed the following documents with the Administrative Law Judge:

(a) the Notice of Hearing as mailed (Exhibit 8);

(b) a copy of the State Register containing the Notice of Hearing and the proposed rules (Exhibit 13);

(c) a copy of the Notice of Solicitation of Outside Opinion published at 17 State Register 1717 (January 4, 1993), together with the materials received in response to that notice (Exhibit 11);

(d) the Agency's certification that its mailing list was accurate and complete and the Affidavit of Mailing the Notice to all persons on the Department's mailing list and to those persons receiving discretionary notice (Exhibits 9-10);

(e) the names of agency personnel and witnesses to testify for the Department at the hearing (Exhibit 12); and

(f) a memorandum transmitting the SONAR to the Legislative Committe to Review Administrative Rules (Exhibit 14).

Statutory Authority and Nature of the Proposed Rules

6. In 1991, the Commissioner of Health adopted extensive rules regarding ionizing radiation. Following the promulgation of those rules, the Legislature enacted a law which delayed the effective date of a number of specified parts of the rules except as they relate to mammographic procedures. The delayed rule provisions included parts 4730.1655 (required quality assurance program procedures) and 4730.1691 (diagnostic quality control tests for a quality assurance program), both of which are involved in

the present rulemaking proceeding. See 1992 Laws of Minnesota, Chapter 444, subd. 1. The legislation provided that the delayed rule provisions would become effective on July 1, 1993, unless they were amended by the Commissioner. The law further directed the Commissioner of Health to review the rules to "determine their appropriateness for and application to medical, dental, chiropractic, podiatric, osteopathic, and veterinary medicine facilities" and to consult with relevant licensing boards and representatives of the affected professions. Id. at subd. 2.

In its Notice of Hearing, the Department relied on Minnesota Statutes §§ 144.05(c), 144.12, subd. 1(15), and 144.121 (1992), in addition to 1992 Laws of Minnesota, Ch. 444, as providing authority for the promulgation of rules relating the use of ionizing radiation. Minn. Stat. § 144.05(c) authorizes the Commissioner of Health to "[e]stablish and enforce health standards for the protection and the promotion of the public's health such as quality of health services, reporting of disease, regulation of health facilities, environmental health hazards and personnel . . . ." Minn. Stat. § 144.12, subd. 1(15) states that the Commissioner "may adopt reasonable rules . . . for the preservation of the public health" and may issue rules controlling "by . . . appropriate means, . . . [s]ources of radiation, and the handling, storage, transportation, use and disposal of radioactive isotopes and fissionable materials . . . ." Minn. Stat. § 144.121 provides for the registration of X-ray machines and periodic radiation safety inspections of sources of ionizing radiation.

In this rulemaking proceeding, the Department proposes to amend the delayed quality assurance provisions of the adopted rules and modify other provisions of chapter 4730 to clarify the rules or correct technical errors. The specific rule parts at issue in this proceeding relate to safety requirements, quality assurance procedures, quality control tests, safety controls for dental radiographic systems, standards for veterinary medicine radiographic systems, and fluoroscopic X-ray systems. The proposed rules establish or modify standards and procedures for using ionizing radiation. The Administrative Law Judge concludes that the Department has general statutory authority to promulgate these rules.

Small Business Considerations in Rulemaking

7. Minn. Stat. § 14.115, subd. 2 (1992), requires state agencies proposing rules that may affect small businesses to consider methods for reducing adverse impact on those businesses. In its Notice of Hearing and Statement of Need and Reasonableness, the Department indicated that it had considered the specific methods indicated in the statute for reducing or eliminating the impact on small business requirements. The Department also asserted that many of the facilities affected by the proposed rules fall within the exemption to the small business requirements set out in Minn. Stat. 14.115, subd. 7(3) (1992) for "service businesses regulated by government bodies, for standards and costs, such as . . . providers of medical care . . . ." Minn. Stat. § 14.115, subd. 7(3) (1992).

The businesses affected by these rules are the practices of physicians, dentists, chiropractors, podiatrists, and veterinarians. While the Department regulates these medical providers by specifying radiation standards and procedures, it has not explained the basis for its assertion that such providers are also regulated by government bodies for costs. The Department

has shown, however, that it would be contrary to the public interest in guarding against unnecessary exposure to ionizing radiation to exempt small practices or adopt less stringent rules with respect to such small businesses. The Minnesota Legislature granted the Department rulemaking authority with respect to the use of ionizing radiation in order to protect persons who come into contact with that health hazard. It would not make sense to protect patients, employees, or members of the public from radiation exposure only if the source of radiation was a large business. It is reasonable for the Department to apply the proposed rules to all businesses in the interest of preserving and protecting public health. The Department thus has met the small business requirements of Minn. Stat. § 14.115, subd. 2 (1992).

Fiscal Note

8. Minn. Stat. § 14.11, subd. 1 (1992), requires agencies proposing rules that will require the expenditure of public funds in excess of $100,000 per year by local public bodies to publish an estimate of the total cost to local public bodies for the two-year period immediately following adoption of the rules. The fiscal note prepared by the Department when it proposed its overall revisions to chapter 4730 of the Minnesota Rules in 1991 estimated that the annual cost of the proposed rules to state and local public bodies during the first two years was $148,441 per year. The Department has concluded that rules at issue in the present rulemaking proceeding will have no significant fiscal impact and may even reduce the above estimate of costs by decreasing the frequency of testing required. Exhibit 5 at 3. The Administrative Law Judge concludes that the Department has met the fiscal notice requirements of Minn. Stat. § 14.11, subd. 1 (1992).

Impact on Agricultural Land

9. Minn. Stat. § 14.11, subd. 2 (1992), requires that agencies proposing rules that have a "direct and substantial adverse impact on agricultural land in the state" comply with the requirements set forth in Minn. Stat. §§ 17.80 to 17.84 (1992). Because the proposed rules will not have an impact on agricultural land within the meaning of Minn. Stat. § 14.11, subd. 2 (1992), these provisions do not apply to this rulemaking proceeding.

Outside Information Solicited

10. In formulating these proposed rules, the Department published a notice soliciting outside information in 17 State Register 1717 (January 4, 1993) and received one responsive comment. Prior to initiating this rulemaking proceeding, the Department also contacted relevant licensing boards and consulted with medical, dental, chiropractic, podiatric, and veterinary medicine facilities and professional organizations. An Advisory Work Group which included representatives from the Minnesota Dental Association, the Minnesota Veterinary Medical Association, and the Minnesota Medical Association, met six to eight times during early 1991 to develop the regulations.

Analysis of the Proposed Rules

11. The Administrative Law Judge must determine, inter alia, whether the need for and reasonableness of the proposed rules has been established by the

Department by an affirmative presentation of fact. The Department prepared a Statement of Need and Reasonableness ("SONAR") in support of the adoption of the proposed rules. At the hearing, the Department primarily relied upon its SONAR as its affirmative presentation of need and reasonableness. The SONAR was supplemented by the comments made by the Department at the public hearing and its written post-hearing comments.

The question of whether a rule is reasonable focuses on whether it has a rational basis. The Minnesota Court of Appeals has held a rule to be reasonable if it is rationally related to the end sought to be achieved by the statute. Broen Memorial Home v. Minnesota Department of Human Services, 364 N.W.2d 436, 440 (Minn.App. 1985); Blocker Outdoor Advertising Company v. Minnesota Department of Transportation, 347 N.W.2d 88, 91 (Minn. App. 1984). The Supreme Court of Minnesota has further defined the burden by requiring that the agency "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken." Manufactured Housing Institute v. Pettersen, 347 N.W.2d 238, 244 (Minn. 1984).

The Administrative Law Judge must also consider whether a rule "has been modified in a way which makes it substantially different from that which was originally proposed." Minn. Stat. § 14.15, subd. 3 (1992). In determining whether a proposed final rule is substantially different, the Administrative Law Judge is to "consider the extent to which it affects classes of persons who could not have reasonably been expected to comment on the proposed rules at the rulemaking hearing, or goes to a new subject matter of significant substantive effect, or makes a major substantive change that was not raised by the original notice of hearing in such a way as to invite reaction at the hearing, or results in a rule fundamentally different in effect from that contained in the notice of hearing." Minn. Rules pt. 1400.1100 (1991).

This Report is generally limited to the discussion of the portions of the proposed rules that received significant critical comment or otherwise need to be examined. Because some sections of the proposed rules were not opposed and were adequately supported by the SONAR, a detailed discussion of each section of the proposed rules is unnecessary. The Administrative Law Judge specifically finds that the Department has demonstrated the need for and reasonableness of the provisions that are not discussed in this Report by an affirmative presentation of facts, that such provisions are specifically authorized by statute, and that there are no other problems that prevent their adoption.

Proposed Rule 4730.1655 - Required Quality Assurance Program Procedures

12. Proposed rule part 4730.1655 sets forth quality assurance measures which must be implemented by all registrants operating diagnostic radiographic facilities. The proposed rules amend subpart 3, item C by specifying two additional documents that may be used by registrants and their employees as sources of information on quality assurance techniques. The proposed rules also permit registrants to incoporate portions of the specified publications into the facility's quality assurance manual. Members of the dental community requested that the Department include references to the two additional documents in the proposed rules. The Department has shown that proposed rule part is needed and reasonable to provide several alternative approaches that may be followed in order to achieve compliance with the rules.

Subpart 2 of the adopted rules provides, inter alia, that "[t]he calibration of any electronic equipment must be traceable to its calibration standard at the National Institute of Standards and Technology (NIST)." Richard A. Geise, Ph.D., a Certified Radiological Physicist with the University of Minnesota Medical School, suggested that subpart 2 be modified to limit traceable calibration to dosimeters, since this is the only instrument for which traceability is needed or available. The Department declined to alter the proposed rule in the manner suggested by Dr. Geise. Even if the current industry practice utilizes only dosimeters, it is not a defect in the rules to incorporate language that is sufficiently flexible to permit the use of other calibration standards which may be developed in the future. Should no changes occur in the future, the existing practice will provide adequate guidance in applying the rule. Subpart 2 thus is found to be needed and reasonable.

Proposed Rule 4730.1691 - Diagnostic Quality Control Tests For a Quality Assurance Program

13. Proposed rule 4730.1691 describes the particular quality control tests which are to be used, the minimum frequency with which such tests are to be conducted, and the minimum performance criteria which are to be satisfied. The proposed rules seek to amend the provisions of subparts 2, 3, 4, 5, 6, 10, 11, and 12. Subpart 2 specifies the quality control testing requirements which are to apply where X-ray film is developed by automatic processing. Subpart 3 mandates that facilities in which X-ray film is developed by manual processing meet the same quality control testing standards which are specified for automatic processing. Tests for all diagnostic radiographic tubes are discussed in subpart 4; tests for facilities with fluoroscopes and C-arm fluoroscopes are discussed in subpart 5; tests for facilities with mammography systems are discussed in subpart 6; tests for facilities with interventional study or vascular imaging systems are discussed in subpart 10; and tests for facilities with dental intraoral and extraoral systems are discussed in subparts 11 and 12. The provisions of the proposed rules which were the subject of significant comment will be discussed below.

Subpart 2 - Automatic Processing

14. Subpart 2 of the rules requires that facilities developing X-ray film by automatic processing conduct three types of tests: (1) quarterly darkroom fog tests; (2) sensitometry and densitometry ("sensi/densi") tests before processing the first film of the day; and (3) temperature checks of the processing equipment at the time of sensitometry. The proposed rules amend the previously-adopted rules by clarifying the Department's intention that the darkroom fog and sensi/densi tests be conducted using film exposed on-site at the time of the test in order to achieve accurate and consistent results.

No one objected to the propriety of using these tests as a part of the quality assurance program of facilities which use automatic processing or to the Department's proposed amendment. Dr. Gray pointed out that one type of processor does not have an internal thermometer with an external gauge and that some disassembly would be required in order to determine the temperature of the developer. He did not, however, suggest any acceptable alternative to measuring the temperature. Dr. Geise questioned whether quarterly darkroom

fog tests were necessary. He suggested that semi-annual testing was adequate and in accordance with recommendations issued by the American College of Radiology (ACR). The Department did not specifically respond to Dr. Geise's comments. The quarterly testing interval was demonstrated to be needed and reasonable during the 1991 rulemaking proceeding. It was included in the rules adopted by the Department as a result of that proceeding and has not been amended during the current proceeding. There is no indication that testing for darkroom fog on a quarterly basis will impose significant costs on facility operators. The Department's designation of a quarterly test interval has been shown to be needed and reasonable.

Dr. Geise also objected to the requirement that sensi/densi testing be conducted "before processing the first film of the day" because such a requirement would work a hardship on hospitals which did not close their X-ray facilities daily. Michael Stone, President of the Board of Podiatric Medicine, questioned whether the cost of daily sensi/densi testing was justified by a benefit to the operator. The Department explained that the language is intended to reduce costs to facilities that do not use X-ray equipment every day by merely requiring that the test be performed on those days when an X-ray is to be taken. The rule does not impose a difficulty for round-the-clock use of equipment, since the facility can designate a standard time when the test will be performed each day.

The Department has demonstrated that subpart 2 is needed and reasonable as proposed to clarify the testing procedures that must be followed in facilities which use automatic processing.

Subpart 3 - Manual Processing

15. As currently proposed, the same three tests required for automatic processing (darkroom fog, sensi/densi, and chemical temperature checks) are also required for facilities which manually process radiographs. As discussed above with respect to automatic processing, the Department has proposed amending the rules to clarify its intent that the darkroom fog and sensi/densi tests be performed using film exposed on-site at the time of the test. The minimum performance criteria required for the darkroom fog and sensi/densi tests are identical regardless of whether the facility uses automatic or manual processing. In facilities using manual processing, the rules specify that temperature checks are required to be conducted before processing each batch of film and the manufacturer's time and temperature chart is to be followed.

No one objected to the requirement in the rules that facilities which utilize manual processing perform quarterly darkroom fog tests and conduct temperature checks before processing each batch of film. These requirements were demonstrated by the Department during the 1991 rulemaking proceeding to be needed and reasonable quality control tests. Numerous individuals objected to the propriety of requiring sensi/densi testing in veterinary facilities. These objections are discussed below. No one objected to the sensi/densi requirements specified in the proposed rules as applied to non-veterinary facilities which utilize manual processing. The Administrative Law Judge finds that the Department has shown the testing standards to be needed and reasonable as applied to non-veterinary facilities.

16. Numerous veterinarians, including David Steiner, Kenneth Detlefsen, Robert Skinner, Ed Clausman, Dick Olson, Daniel Feeney, M.J. Reinhiller, Scott Greiman, Paul Zollman, George Baker, Jeff Johnson, Donald Sime, D.D. Hartman, Joanne Schulman, Kevin Barcus, Bruce Schnabel, Fred Pomeroy, William Funk, Cathy Ellis, and Bradford Yoho, objected to the rules' requirement that sensi/densi tests be performed before processing the first film of the day and urged that veterinary facilities be exempted from the sensi/densi testing requirement. Sensi/densi tests are procedures which evaluate the developing process in an effort to ensure that films are being developed to optimal levels. The goal of sensi/densi tests is to keep the X-ray dose as low as possible while achieving good quality images. They are conducted using a sensitometer (a light-producing instrument used to give a known exposure to X-ray film) and a densitometer (an instrument used to measure the film density of the processed sensitometric strips). Film is first exposed to a measured dose of radiation from the sensitometer. The film is then developed and the developed film is compared to the standard results to assess the degree of developer quality. If the test results fall outside allowable parameters, it is necessary to investigate and correct the problem before processing additional films. Corrective action may involve adjusting the developer chemicals, the temperature, or development time. Due to the nature of the testing device which is used, the sensi/densi test does not result in additional radiation exposure. Because problems are corrected before the first X-ray exposure, retakes due to poor developer quality are eliminated.

General information was provided by the Department and by Joel E. Gray, Professor of Radiologic Physics with the Mayo Clinic, concerning the efficacy of sensi/densi testing as a quality control measure. This information did not specifically address the conditions which prevail at veterinary facilities. The materials and information provided indicated that fifty percent of medicial facilities nationwide (excluding veterinary facilities) are underprocessing their X-ray film. Dr. Gray pointed out that underprocessing reduces the speed of the film and the quality of the image. In such situations, since the images are not dark enough, the technicians then increase the radiation dose to the patient in order to obtain better images. Exposure to ionizing radiation has a potentially harmful impact on health and its effects are cumulative. Dr. Gray noted as a general matter that "[u]nderprocessing decreases image quality, increases patient and staff radiation, and increases the potential for patient motion which results in an increased number of films which must be retaken, thereby further increasing the radiation dose to the staff." Dept. Ex. 21. The information submitted indicates that the use of sensi/densi tests and other photographic processing quality control methods has generally been shown to reduce radiation dose to facility staff by increasing the speed of the film. Lesser amounts of radiation will thereby be required for each film, the number of films which must be retaken due to patient motion will decrease, and the quality of the X-ray images will be improved. By avoiding unnecessary retakes, the exposure of staff to scattered radiation will be reduced.

The veterinarians opposed to the application of sensi/densi testing in their facilities argued that sensi/densi testing is only beneficial where facilities utilize automatic processing or modern X-ray systems capable of exposures as brief as 1/120 of a second. They pointed out that their animal patients often have only one or two X-ray exposures during their entire lifetimes and thus have far fewer exposures to ionizing radiation than

humans. They further emphasized that it is rare for veterinarians to have to retake X-rays due to poor developing procedures. In most practices, such retakes do not exceed two or three a year. The vast majority of retakes are due to animal movement during the X-ray procedure or improper exposure settings due to differences in animal sizes and species. In addition, veterinary X-rays are usually undertaken in order to detect fractures, bladder stones, large masses, cardiac silhouettes, or other problems where there is considerable difference in tissue densities, and thus do not require the same level of detail as is required in diagnostic imaging for human medical needs. The commentators stressed that two-thirds of the veterinarians in the State take less than one X-ray per day. Veterinarians tend for the most part to use older human X-ray equipment which, while inspected by the Department to ensure safety, does not permit the brief exposures (1/120th of a second) used at present in state-of-the-art human X-ray equipment.

The commentators asserted that seventy-five percent of the private veterinary practices in Minnesota manually process X-ray films using hand tanks which lack the precise time and temperature controls of automatic processors. They argued that sensi/densi testing is inappropriate because it requires more precision than is obtainable by veterinarians using hand tank processing. Dr. Steiner testified that he utilized sensi/densi testing over a twelve-month period and found that "the readings wandered out of parameters and returned to normal ranges of their own accord, with no changes other than a new day and a fresh pair of hands." Throughout that time, no retakes were required due to poor image quality caused by inadequate processing. The veterinarians argue that this evidence demonstrates the sensi/densi test should not be required in veterinarian uses of manual processing. Finally, the veterinarians objected to the approximately $1,000 in additional costs required for sensi/densi testing equipment and emphasized that, in the absence of insurance, these costs would be borne by the pet-owning public. They urged the Department to mandate the wearing of radiation monitoring badges or the use of film identification printers or presensitized sensitometry strips as an alternative to requiring sensi/densi testing.

The Department and Dr. Gray responded that veterinarians, like other health professionals, need quality images for correct diagnosis and treatment. They emphasized that veterinarians and technicians are frequently required to hold the animals being X-rayed and are therefore exposed to scattered radiation. Although such individuals may wear badges which detect such exposures, the badges do not register exposures below the threshold level of 10 millirems and obviously do not in themselves protect the individual from exposure. The Department indicated that the film identification printers or presensitized strips did not provide accuracy and precision equivalent to sensi/densi testing. Dr. Gray asserted that Dr. Steiner's data in fact shows that sensi/densi testing is needed in veterinary medicine. Dr. Gray contended that sensi/densi is appropriate even where hand tanks are used and asserted that better quality control in developing techniques would enable veterinarians to reduce the radiation exposure in their clinics. He further argued that more exacting image development ensures that a good diagnostic image will be obtained with a lower radiation dosage.

The primary argument in favor of sensi/densi testing thus is that the improved quality of X-ray image development allows reduction of exposure time for the patient (and thereby any person holding the patient). Dr. Clausen and

other veterinarians stated, however, that they already use the shortest interval available on their X-ray equipment (1/10 of a second). The Department responded:

> The department notes that if this is true they are using the same equipment settings when X-raying a cat or a large dog. Thus they may be frequently overexposing the veterinarian and/or technician. As veterinarians purchase more modern X-ray equipment, with shorter time intervals for exposure (typically 1/120 of a second), this problem will be resolved. X-ray machine limitations do not justify poor film processing.

Department's April 12, 1993, Response at 2.

17. The record demonstrates that sensi/densi testing within the proposed parameters before the first X-ray of the day does assist in ensuring that an adequate diagnostic image is obtained at the lowest possible radiation dose in veterinary facilities where (1) automatic processing is used or (2) manual processing is used in conjunction with "modern" X-ray equipment (i.e., equipment which has a minimum time interval for exposure of 1/120 of a second). Where manual processing is used in conjunction with "older" equipment (i.e., equipment which has a minimum time interval for exposure that exceeds 1/120 of a second), however, routine sensi/densi testing is neither needed nor reasonable. First, the Department has not established the need for sensi/densi testing in such instances. There has been no showing that poor film processing is in fact a problem with respect to veterinary facilities. Poor film processing would require retakes. The evidence submitted establishes that retakes due to processing problems are extremely rare in veterinary medicine. Second, the Department has not demonstrated that the use of sensi/densi testing in veterinary facilities using manual processing and older equipment is reasonable. The Department has not shown that the performance of sensi/densi testing in such settings accurately predicts the likelihood that an adequate image will be obtained. Indeed, the evidence submitted by the veterinarians supports the contrary inference that there is no rational relationship between the results of sensi/densi testing and the primary goals to be attained by such testing (i.e., obtaining a good quality image with the shortest possible radiation exposure) in veterinary settings involving manual processing and older equipment. Moreover, because veterinarians using older equipment are in most instances already utilizing the briefest exposure setting possible given the limitations of their equipment, sensi/densi testing will not enable them to reduce radiation doses. The Department thus has not shown that the sensi/densi testing requirement is needed and reasonable when applied to veterinary facilities which utilize manual processing and X-ray systems that have minimum time intervals for exposure longer than 1/120 of a second, and the rules are defective in this regard.

The rule as presently proposed does not require performance of sensi/densi testing only where retakes due to poor processing are necessary, but instead requires rote performance of sensi/densi testing prior to the first film processing of the day. In situations in which veterinarians in

fact obtain an X-ray image which is of poor quality, it is both needed and reasonable to require them to employ sensi/densi testing in order that they may determine whether the developer is at fault. To cure the defect noted above and incorporate an appropriate testing requirement, the Administrative Law Judge suggests that a new item D be added to part 4730.2050, subpart 1, containing language similar to the following:

> D. Veterinary medicine radiographic installations which utilize X-ray equipment with a minimum exposure setting longer than 1/120 of a second need not meet the frequency requirement for sensitometry and densitometry testing specified in part 4730.1691, subpart 3.B. Such installations must, at a minimum, conduct sensitometry and densitometry testing as described in part 4730.1691, subpart 3.B., prior to retaking an X-ray whenever a film is unuseable due to poor processing.

The suggested language does not relieve veterinary facilities of the need to perform sensi/densi testing, but it does limit the conditions under which the testing is required. Sensi/densi testing would continue to be required where a poor quality film has been obtained due to a processing problem (rather than animal movement). In such situations, the veterinarian or technician must perform the testing prior to taking an additional X-ray and adjust the developer in order to ensure that a useable image will be obtained. Veterinary facilities would remain free to conduct such testing on a more frequent basis if they choose to do so and would be required to comply with part 4730.1691 should they upgrade to automatic processing or modern X-ray equipment.

If the Department seeks to monitor the frequency of processing problems in veterinary facilities and assess the efficacy of sensi/densi testing in such facilities, it may add the following language to part 4730.2050, subp.1.D.:

> Any veterinary medicine radiographic installations which must conduct a sensitometer and densitometer test under this item must report that fact to the Department within one week of the test date, together with the test results.

The additional language would impose a reporting requirement on veterinarians using manual processing and older equipment. The record strongly suggests, however, that such reports will be the relatively infrequent. The data collected may be useful in assessing whether it would be appropriate to modify the standard for sensi/densi testing in the future. The first suggested modification cures the defect in the proposed rule and is needed and reasonable. Neither of the changes suggested in this Finding are substantial changes.

Subpart 4 - All Diagnostic Radiographic Tubes; Required When Applicable

18. Subpart 4 specifies numerous types of tests which are to be performed with respect to diagnostic radiographic tubes. As adopted in 1991, the rules set forth a requirement that these tests be performed annually. The annual testing requirement was found to be needed and reasonable in the 1991

rulemaking. In the Matter of the Proposed Adoption of the Rule of the Minnesota Department of Health Governing Sources of Ionizing Radiation, Minn. Rules 4730 at 19 (Report issued June 20, 1991). The Minnesota Legislature delayed the effective date of this portion of the rules and directed the Commissioner to consult with affected persons and appropriate boards. Based upon that consultation, the Department has proposed that subpart 4 be amended to require only biennial testing. The tests involved in this portion of the proposed rules are directed at the actual X-ray machinery and provide assurance that the devices are operating within appropriate time, intensity, and radiation levels. The previous finding of need and reasonableness of an annual testing interval does not preclude the Department from selecting another standard. No one suggested that the two-year testing frequency is not suitable for diagnostic radiographic tubes. One commentator, Bill Korlath of Mithun-Oliver X-ray, Inc., suggested that X-ray systems be divided into two categories and that those that are less than five kilowatts be calibrated every two years and those that are five kilowatts or more be calibrated every year. The Department did not discuss Mr. Korlath's concerns in its post-hearing submission. Mr. Korlath did not provide sufficient factual information to demonstrate that the approach followed in the proposed rules is unreasonable. The Administrative Law Judge thus concludes that the Department has demonstrated that the two-year minimum test interval is needed and reasonable.

19. Under item H, timer accuracy must be within ± 5% of the setting for electronic equipment or meet the requirement in an associated table for mechanical timers. Dr. Geise suggested that the accuracy for electronic timers be set at ± 10% and that the reference to the table be deleted, since it refers to obsolete equipment. He asserts that the ± 5% standard will be unduly difficult to meet for older equipment and that a failure to meet that standard will not adversely affect image quality. Dr. Geise did not discuss whether allowing a less stringent standard could result in additional radiation exposure to patients and radiation technicians. As the rule presently reads, even if the timer does not fall within the ± 5% standard, it need only be adjusted once every two years. This outcome does not impose an undue burden on the facility. Item H is needed and reasonable, as proposed.

20. Chuck Doerr and Bill Korlath objected to certain of the quality assurance standards as violative of federal certification standards set forth in 21 C.F.R. subchapter J or as potentially imposing civil liability on the state with respect to noncertified equipment. Item J of subpart 4 provides that certified equipment must follow the manufacturer's specified limits and sets a minimum performance criterion for noncertified equipment which corresponds with the NCRP recommendations set forth in Report No. 99. The Department has demonstrated that noncertified equipment must meet specified standards. The commentators have not shown that the rule improperly preempts federal standards or shifts liability from the manufacturer to the State. No alternative standard has been suggested. For these reasons, the Administrative Law Judge finds that item J of the proposed rules has been shown to be needed and reasonable.

Subpart 5 - For Facilities With Fluoroscopes and C-arm Fluoroscopes, Except Radiation Therapy Simulators

21. As originally adopted, subpart 5 required that diagnostic quality control tests with respect to facilities with fluoroscopes and C-arm

fluoroscopes (except radiation therapy simulators) be performed at a minimum on an annual basis. The Legislature delayed the effective date of this portion of the proposed rules. After consulting with affected persons and groups, the Department has proposed to amend subpart 5 to require biennial rather than annual testing. Dr. Geise objected to the modification proposed by the Department since this equipment is capable of delivering high doses of radiation which can be harmful to patients and radiation technicians. Bruce Libey, a Consulting Medical Physicist with Radiation Physics Consultants, Inc., agreed with this objection and suggested that the annual minimum testing interval was preferable. In its SONAR, the Department indicated that industry representatives recommended that period and that a biennial testing frequency would be consistent with that required for other diagnostic radiography systems which have a similar dose output. The Department did not otherwise respond to the comments of Mssrs. Geise and Libey or offer any further factual information to support its designation of a biennial testing requirement.

As previously discussed, the Department has the burden of showing the need for and reasonableness of its proposed rules by an affirmative presentation of fact. The presentation may consist of adjudicative facts, legislative facts, statutory interpretation, or articulated policy preferences. St. Paul Area Chamber of Commerce v. Minnesota Public Service Commission, 251 N.W.2d 350, 356-57 (Minn. 1977); 1 & 2 Davis, Administrative Law Treatise §6.13-14, 12.3 (2d Ed.) In this instance, the Department has not met its required burden to show that biennial testing is needed or reasonable for fluoroscopes or C-arm fluoroscopes. The Department has three options to correct this defect. First, by withdrawing the proposed amendment to subpart 5, the already-adopted annual testing requirement will be retained. That testing frequency was previously shown in the 1991 rulemaking to be needed and reasonable to conform to national standards. Second, the Department may take the issue to the Legislative Commission to Review Admininstrative Rules (LCRAR) for its advice and comment. Finally, the Department may choose to reconvene this hearing on the limited issue of the biennial testing requirement set forth in subpart 5 by preparing a supplemental SONAR, sending notice to all individuals who signed the hearing register and who received notice of the March 15 hearing, and publishing a notice in the State Register.

Subpart 8 - For Facilities With Computed Tomography Scanners

22. Dr. Geise suggested the the rule on low contrast phantoms was "expensive and unnecessary for testing the ability of a scanner to detect low contrast objects." He suggested an alternative method of testing using a baseline measurement which he suggested would provide better accuracy at lower cost. The Department did not propose to modify any portion of subpart 8 during this proceeding. The subpart was demonstrated to be needed and reasonable during the 1991 rulemaking proceeding and has been adopted as a rule by the Commissioner. The Department is not obligated to demonstrate the need for and reasonableness of that subpart again in this proceeding. The Department is, however, urged to consider the suggestion and, if appropriate, modify the subpart to include a reference to the alternative standard suggested by Dr. Geise.

Subpart 10 - For Facilities With Interventional Study or Vascular Imaging Systems

23. The Department proposes to amend the heading of this subpart to clarify that it applies to facilities with "interventional study or vascular

imaging systems" and not just to facilities with cardiac catheterization systems. In its SONAR, the Department indicates that the modification is reasonable because systems similar to cardiac catheterization are used to visualize other parts of the body and the same kind of tests are employed in these situations to ensure proper imaging results. The Department has not otherwise amended the provisions of subpart 10, and thus has retained the requirement that interventional studies and vascular imaging tests must continue to be performed semi-annually.

Dr. Geise suggested that items F, G, and H in subpart 10 be moved to subpart 9. He also indicated that item F was too restrictive and may increase radiation exposure by requiring multiple exposures. Dr. Geise recommended that the maximum allowable dosage level be increased to reduce the need for retakes. He did not suggest what the uppermost level should be. As discussed above with respect to subpart 8, the portions of the rules to which Dr. Geise objects have already been shown to be needed and reasonable. The Department should consider Mr. Geise's comment, but the subpart is not defective as it currently is framed.

Allowing Alternatives Approved by Physicist

24. Minn. Rules pt. 4730.1475 (1991) authorize the Commissioner to grant a variance from the requirements of the ionizing radiation rules only according to the criteria and procedures specified in Minn. Rules parts 4717.7000 to 4717.7050. Minn. Rules pt. 4717.7040 allows the Commissioner to grant a variance only if the variance is properly requested, no potential adverse effect exists, the alternative measures meet or exceed the rule standards, an undue burden is imposed by strict compliance with the rules, and no statutory standard is violated. Dr. Geise suggested that variances from the rule provisions be allowed, but objected to a variance process requiring application to the Department. He recommended that a radiological physicist or diagnostic radiological physicist with specified credentials and experience be allowed to approve variances. The Department declined to adopt this suggestion.

The Minnesota Legislature has authorized the Department of Health to regulate the use of ionizing radiation. It is reasonable to require that variances from the rules be granted only if it is demonstrated to the satisfaction of the agency with regulatory responsiblity that the variance is appropriate. The existing rules set forth standards which must be followed by the Commissioner in making determinations concerning variance requests. The health and safety of the public may not be adequately protected if variances were granted based solely on the recommendation of a physicist. The Department's decision to decline to allow physicists to approve variances to the provisions of the proposed rules does not render them unreasonable or defective. Moreover, adoption of the suggested approach would also have constituted a substantial change from the rules as originally proposed.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Department of Health ("the Department") gave proper notice of this rulemaking hearing.

2. The Department has fulfilled the procedural requirements of Minn. Stat. §§ 14.14, subds. 1, 1a, and 2 (1992), and all other procedural requirements of law or rule so as to allow it to adopt the proposed rules.

3. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3, and 14.50 (i) and (ii) (1992).

4. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2, and 14.50 (iii) (1992), except as noted in Findings 17 and 21.

5. The additions and amendments to the proposed rules which were suggested in this Report after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3 (1992), and Minn. Rules pts. 1400.1000, subp. 1 (1991).

6. The Administrative Law Judge has suggested action to correct the defects cited at Conclusion 4 as noted in Findings 17 and 21.

7. Due to Conclusions 4 and 6, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3 (1992).

8. Any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

9. A Finding or Conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted in accordance with the Findings and Conclusions in this Report except where specifically otherwise noted above.

Dated this 14th day of May, 1993.

Barbara L. Neilson

BARBARA L. NEILSON
Administrative Law Judge

Reported: Taped; no transcript prepared.