STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE

MINNESOTA
BOARD OF DENTISTRY

In the Matter of the Proposed Adoption of Rules of the Board of Dentistry Relating to Licensure.

STATEMENT OF NEED

AND REASONABLENESS

I. INTRODUCTION

Pursuant to Minnesota Statutes section 14.23 (1990), the Minnesota Board of Dentistry (hereinafter "Board") hereby affirmatively presents the need for and facts establishing the reasonableness of the Board's proposed amendments to Minnesota Rules part 3100.0100, subparts 2, 2a, 2b, 8a, 9a, 9b, 12a and 15a relating to definitions; parts 3100.1100, subparts 1D and 6, 3100.1200, subparts 1, 1G and 2 and 3100.3600, subparts 1, 2, 3, 4, 5, 6, 7 and 8 relating to the training and educational requirements for the administration of anesthesia and sedation and the reporting of incidents arising from the administration of anesthesia and sedation; part 3100.6200 K, L, and M relating to the definition of "conduct unbecoming a person licensed to practice dentistry or dental hygiene or registered as a dental assistant or conduct contrary to the best interests of the public"; part 3100.6300, subparts 1, 11, 12 and 13 relating to minimum safety and sanitary conditions in the areas of infection control,

the disposal of sharps and contaminated waste, and the presence of staff certified in basic life support; part 3100.8500, subparts 1 and 1a relating to the permissible duties of registered dental assistants, including permissible duties under direct and indirect supervision; and part 3100.8700, subparts 1, 2 and 2a relating to the permissible duties of dental hygienists, including permissible duties under general, direct and indirect supervision.

II. Statutory Authority

The statutory authority of the Board to adopt these rules is as follows:

1) Minnesota Statutes section 150A.04, subdivision 5 (1990), authorizes the Board to promulgate rules as are necessary to carry out and make effective the provisions and purposes of the Minnesota Dental Practices Act, Minnesota Statutes Chapter 150A, including specifying training and education necessary for administering general anesthesia and intravenous conscious sedation;

2) Minnesota Statutes section 150A.06, subdivisions 1 and 2 (1990), authorizes the Board to license dentists and dental hygienists who have met education, examination and training requirements prescribed by the Board;

3) Minnesota Statutes section 150A.08, subdivision 1 (6) (1990), authorizes the Board define in its rules conduct which is unbecoming a licensee or registrant;

4) Minnesota Statutes section 150A.08, subdivision 1 (10)

(1990), authorizes the Board to establish standards in its rules governing adequate safety and sanitary conditions for dental offices; and

5) Minnesota Statutes section 150A.10, subdivisions 1 and 2 (1990), authorizes the Board to promulgate rules governing the permissible duties of dental hygienists and dental assistants.

III. Compliance With Procedural Rulemaking Requirements

A. Requirements in General

At its meeting on Saturday, September 21, 1991, the Board elected to follow the procedures set forth in Minnesota Statutes sections 14.05 to 14.20 (1990), which govern the adoption of rules after a public hearing.

Pursuant to Minnesota Statutes section, 14.131 (1990), the Board has prepared this statement of need and reasonableness and will make it available to the public prior to publishing the notice of the rules hearing. The Board also will provide a copy of this statement of need and reasonableness to the Legislative Commission To Review Administration Rules when it becomes available for public review.

The Board will publish in the State Register the proposed rules and a notice of the rules hearing. The Board also will mail copies of the notice to persons registered with the Board pursuant to Minnesota Statutes section 14.14, subdivision 1a (1990). The notice will comply with the requirements of Minnesota Statutes section 14.14, subdivision 1a (1990) and Minnesota Rules parts 1400.0300,subpart 1a and 1400.0400 (1991).

B. Notice of Intent to Solicit Outside Information

Minnesota Statutes section 14.10 (1990) requires that an agency which seeks information or opinions from sources outside the agency in preparing to propose the adoption or amendment of rules must publish notice of its action in the State Register and afford all interested persons an opportunity to submit data or comments on the subject of concern in writing or orally. In the State Register issue dated June 30, 1986, Volume 10, Number 53 the Board published a notice entitled "Opinions Sought on Rules About Auxiliary Personnel and on General Anesthesia and Intravenous Conscious Sedation."

On June 15, 1988, the Board mailed to all interested parties notice of an open public forum to be held on June 25, 1988, for the purpose of presenting, discussing and exchanging ideas relating to the Board's proposed rule amendments. The public forum was held on June 25, 1988, and was presided over by Dr. Robert Hoover, then chair of the Board's rules committee.

The Board held a second open public forum on July 26, 1988 and held two informational meetings in conjunction with the Minnesota Dental Association's Annual Star of the North Meeting -- the first in April 1987 and the second in April 1988. In addition, the Board conducted public rules committee meetings to discuss proposed rule changes on June 1, 1987, January 27, 1988, May 26, 1988, November 17, 1988 and May 2, 1989. Finally, in its November 1987 and November 1988 newsletters the Board published a listing of subject areas to be considered by the Board in amending its rules.

The rules now being proposed by the Board are the result of the above referenced efforts at gathering input from the dental community and the public in the areas of anesthesia and sedation and auxiliary duties.

C. Expenditure of Public Monies and Impact on Agricultural Land

The adoption of these rules will not result in the expenditure of public monies by local public bodies in either of the two years following promulgation, nor do the rules have any impact on agricultural land. Therefore, no further information need be provided under Minnesota Statutes section 14.11 (1990).

D. Small Business Considerations

Minnesota Statutes section 14.115 (1990) requires administrative agencies, when proposing rules, to consider various methods for reducing the impact of the proposed rules on small businesses and to provide the opportunity for small businesses to participate in the rulemaking process. The policy behind this statute is clearly to protect small businesses. However, section 14.115, subdivision 7 states that "agency rules that do not affect small businesses directly" are not to be bound by this section.

It is the position of the Board that Minnesota Statutes section 14.115, relating to small business considerations in rulemaking, does not apply to these proposed rules insofar as the rules do not affect small businesses directly. The Board's authority relates only to dental health care workers and not to the dental businesses they operate. While it is true that someone

cannot operate a dental business without being licensed as a dentist by the Board, a license runs to the ability of the dental health care worker to provide dental services for the purpose of public protection and not to the business aspects of operating a dental office. This is graphically illustrated in recent dealings with nondentists who are involved with dental franchise offices. The Board has not prohibited nondentists from becoming involved in operating a dental business. Rather, it is the Board's position that nondentists may not interfere with or have any control over the dentists when it comes to any aspect of the practice which could affect the provision of dental services to a patient. In sum, these proposed rules would regulate the provision of dental services not the dental business. Therefore, the Board believes it is exempt from reducing the impact of these proposed rules on small businesses under Minnesota Statutes section 14.115, subdivision 7b (1990).

The Board believes it is also exempt from the provisions of section 14.115 pursuant to subdivision 7c, which states that section 14.115 does not apply to "service businesses regulated by government bodies, for standards and costs, such as ... providers of medical care." Dental health care workers provide medical care and are regulated for standards and costs. The Board regulates dental health care workers for standards and the Minnesota Department of Human Services regulates them for costs.

It is the Board's position that the same government body need not regulate the service business for standards and costs in order

for the exemption in subdivision 7c to apply, for two reasons. First, the provision specifically refers to regulation by "government bodies," and thus clearly anticipates regulation by more than one government body. Second, and more significantly, some of the examples listed in subdivision 7c of service businesses exempt from the conditions of section 14.115 actually would not qualify for the exemption if the same government body had to regulate for standards and costs. For example, nursing homes and hospitals are regulated by different government bodies for standards and costs. The Minnesota Department of Health regulates them for standards and the Minnesota Department of Human Services regulates them for costs. If the legislature had intended to exempt from the scope of section 14.115 only those rules addressing service businesses regulated by one government body for standards and costs, then it could not have included nursing homes and hospitals in its list of exemptions.

Based on the foregoing, it is clear that section 14.115 is not intended to apply to rules promulgated by the Board. However, should these proposed rules in some way be construed as directly affecting small businesses, the Board has considered the five suggested methods listed in section 14.115, subdivision 2, for reducing the impact of the proposed rules on small businesses. The five suggested methods enumerated in subdivision 2 are as follows:

a) the establishment of less stringent compliance or reporting requirements for small businesses;

b) the establishment of less stringent schedules or deadlines

for compliance or reporting requirements for small businesses;

c) the consolidation or simplification of compliance or reporting requirements for small businesses;

d) the establishment of performance standards for small businesses to replace design or operational standards required in the rule; and

e) the exemption of small businesses from any or all requirements of the rule.

The Board has considered the feasibility of implementing each of the five suggested methods, considered whether implementing any of the five methods would be consistent with the statutory objectives that are the basis for this rulemaking, and concluded the following:

1. It would not be feasible to incorporate any of the five suggested methods into these proposed rules.

Methods (a)-(c) of subdivision 2 relate to lessening compliance or reporting requirements for small businesses either by (a) establishing less stringent requirements, (b) establishing less stringent schedules or deadlines for compliance with the requirements, or (c) consolidating or simplifying the requirements. Since the Board is not proposing any compliance or reporting requirements for either small or large businesses, it follows that there is no such requirements for the Board to lessen with respect to small businesses. If, however, these proposed rules are viewed as compliance or reporting requirements for businesses, then the Board finds that it would be unworkable to lessen the requirements

for those dental health care workers who are in a business setting with fewer than 50 employees, since that would include the vast majority of dental health care workers. Therefore, lessening the requirements for dental health care workers in business settings with 50 employees or fewer would be unworkable because the lessened requirements would then be the predominant requirement, not the exception.

Method (d) suggests replacing design or operational standards with performance standards for small businesses. The Board is not proposing design or operational standards for businesses, and therefore there is no reason to implement performance standards for small businesses as a replacement for design or operational standards that do not exist.

Finally, method (e) suggests exempting small businesses from any or all requirements of the rules. Under the Board's view that these proposed rules do not in any way regulate the business operation of dental health care workers, there are no rule requirements from which to exempt small businesses. However, if these proposed rules are viewed as regulating businesses insofar as they regulate dental health care workers, then it would hardly make sense for the Board to exempt from these rules those dental health care workers who practice in a business setting with fewer than 50 employees, since they constitute the vast majority of dental health care workers. For all these reasons, it is not feasible for the Board to incorporate into these proposed rules any of the five

methods specified in subdivision 2 of the small business statute.

2. Reducing the impact of these rules on small businesses would undermine the objective of the Dental Practices Act.

Pursuant to Minnesota Statutes section 150A.04, subdivision 5, the Board's duty is To promulgate rules to make effective the Dental Practices Act. Presumably those rules should apply equally to and govern all applicants, licensees and registrants, regardless of the size of the business setting. As stated above, it is the Board's position that the proposed rules will not directly affect small businesses, and do not have the potential for imposing a greater impact on dental health care workers in a setting with fewer than 50 employees than on dental health care workers in a large business setting. It has also been explained above that the Board considers it unfeasible to implement any of the five suggested methods enumerated in subdivision 2 of the small business statute.

Nonetheless, to the extent that the proposed rules may affect the business operation of a dental health care worker and to the extent it may be feasible to implement any of the suggested methods for lessening the impact on small businesses, the Board believes it would be unwise and contrary to the purposes to be served by these rules to exempt one group of dental health care workers -- indeed, the majority of dental health care workers -- from the requirements of these proposed rules.

It would be contrary to the Board's statutory authority to adopt one set of regulations that would apply to those dental

health care workers who work in a large business setting and adopt another less stringent set of regulations to be applied to those dental health care workers who work in a small business setting. It is the Board's view that these proposed rules must apply equally to all dental health care workers if the public whom they serve is to be adequately protected.

3. Small business will have the opportunity to participate in the rulemaking process.

Regardless of whether dental health care workers are considered as individuals or small businesses, they will have an opportunity to participate in the rulemaking process. A notice of the proposed rulemaking will be mailed to the following organizations which will likely represent any entity affected by the rules which might claim to be a small business:

1) St Paul District Dental Society;
2) Minnesota Dental Hygiene Association;
3) Minnesota Dental Association;
4) Minneapolis District Dental Society;
5) Minnesota Medical Association;
6) Minnesota Dental Lab Association;
7) Midwest Society of Oral Surgery;
8) Minnesota Dental Assistants Association;
9) Northwest District Dental Society;
10) Zumbro Valley Dental Society;
11) West Central District Dental Society;
13) Minnesota Periodontists Association;

14) Northeast District Dental Society; and

15) Southeast District Dental Society.

A notice of the proposed rulemaking will also be mailed to all those who have requested to be on the Board's mailing list.

In addition to mailing the notice as described above, the Board has maintained informal contact with members of the professional associations representing dental health care workers regarding the proposed rules since beginning this process in 1986. The Board has also hosted two open public forums, two informational meetings and numerous public rules committee meetings over the past several years.

IV. NEED FOR AND REASONABLENESS OF THE PROPOSED RULES

A. General Statement of Need and Reasonableness

In order to amend administrative rules, an agency must demonstrate that the proposed rule changes are needed and reasonable. It is the Board of Dentistry's judgment that the proposed rule changes addressed herein more clearly delineate the provisions of the Minnesota Dental Practices Act for the purpose of safeguarding the public welfare and promoting the best interests of the dental profession, and that they have a rational basis in both law and dentistry as detailed below.

B. The Need For and Reasonableness of the Definitions

It is the Board's view that the definitions proposed in Minnesota Rules part 3100.0100, subparts 2, 2a, 2b, 8a, 9a, 12a and 15a are needed because they are terms which are used throughout the proposed rules. The definitions are reasonable because they affect

the commonly accepted usage of the terms among professionals in the dental community.

C. The Need For and Reasonableness of the Additional Training Educational Requirements For The Administration Of General Anesthesia, Conscious Sedation and Nitrous Oxide Inhalation Analgesia.

1. Historical background leading to proposed rule changes

Pain is a major factor that brings patients to the dental office, while fear and anxiety about pain are common reasons patients fail to seek dental care. The magnitude of this public health problem is indicated by the fact that there are 35 million people who avoid dental treatment until forced into the office with a toothache according to the National Institute of Dental Research the control of pain and anxiety is therefore an essential part of dental practice.

The practice of dentistry has long involved the administration of drugs to the body for control of pain. To accomplish this purpose, various techniques are used today, including local anesthetics and agents. The choice of the most appropriate modality for a particular situation is based on the training, knowledge, and experience of the dentist; the nature, severity, and duration of the procedure; the age and physical and psychological status of the patient; the level of fear and anxiety; and the patient's previous response to pain control procedures.

2. The differences between general anesthesia, deep sedation, conscious sedation and nitrous oxide inhalation analgesia.

Drugs that depress the central nervous system produce a

progressive dose-related continuation of effects. Small doses produce light sedation. In this state, the patient remains conscious, with some alteration of mood, relief of anxiety, drowsiness, and sometimes analgesia; which is the diminution or elimination of pain in the conscious patient. As the drug is increased, or as other drugs are added, greater central nervous system depression occurs, resulting in deepening of sedation and sleep from which the patient can be aroused. Finally, when consciousness is lost and the patient cannot be aroused, light general anesthesia begins. General anesthesia can be deepened by additional drug administration. The amount of training, experience and skill needed to safely produce and manage central nervous system depression increases with the degree of depression involved.

The degree and duration of central nervous system depression required varies with the procedure being performed and with the special requirements of the patient; these may be altered during the procedure as operative requirements change. Only a brief period of central nervous system depression may be necessary to permit the performance of procedures such as administration of a local anesthetic or the uncomplicated extraction of a tooth.

The most commonly used and accepted pharmacologic approaches for the relief of pain and anxiety in dentistry are local anesthesia, sedation (conscious or deep) and general anesthesia. local anesthetics are used to control regional pain in the conscious patient, usually by the topical application or regional injection of a drug.

Sedation describes a depressed level of consciousness, which may vary from light to deep. At light levels, termed conscious sedation, the patient retains the ability present before sedation to independently and continuously maintain airway and respond appropriately to verbal command (e.g. "open your eyes") and physical stimulation. This minimally depressed level of consciousness can be produced by either a pharmacologic or non-pharmacologic method, or a combination thereof. The patient may have amnesia, and protective reflexes are normally or minimally altered. In deep sedation, some depression of protective reflexes occurs, and although more difficult, it is still possible to arouse the patient. For the anxious adult patient, sedation provides a calming effect and the addition of local anesthesia provides the relief of pain or discomfort. Sedation may also be indicated to minimize stress in the presence of certain medical conditions (e.g. hypertension) and for complex procedures requiring an extended period of operating time.

Nitrous oxide inhalation analgesia is probably the most widely used form of conscious sedation in dentistry today. It involves the administration by inhalation of a combination of nitrous oxide and oxygen, thereby producing an altered level of consciousness. The state of relative analgesia induced by nitrous oxide and oxygen results in a calm and relaxed patient whose sensitivity to pain is greatly reduced. This increased tolerance for dental procedures enhances the dentist's or dental hygienist's ability to provide

quality treatment to the anxious patient.

General anesthesia describes a controlled state of unconsciousness, accompanied by partial or complete loss of protective reflexes, including the inability to independently maintain an airway and respond purposefully to verbal command, produced by a pharmacologic or non-pharmacologic method, or a combination thereof. It is generally used with healthy adult and pediatric patients when there is a greater complexity of the procedure, higher levels of preoperative anxiety, or a greater need for a pain-free operative period. A contraindication to local anesthesia might also require that a general anesthetic be administered.

3. <u>The appropriate agents and techniques for general anesthesia and sedation.</u>

According to the National Institute of Dental Research, the drug groups used for sedation or general anesthesia in the dental office are essentially the same as those used in the hospital setting. These groups include benzodiazepines (e.g. diazepam), barbiturates (e.g. pentobarbital), alcohols (e.g. chlorohydrate), the opioid analgesics (e.g. meperidine, fentanyl), antihistamines (e.g. diphenhydramine, hydroxyzine), phenothiazines (e.g. promethazine) and nitrous oxide/oxygen.

Drugs that in low dosage produce sedation, but are generally recognized as general anesthetics, are the halogenated inhalation agents (e.g. enflurone), ultra-short acting barbiturates (e.g. thropental, methohexital), and the dissociative agent ketamine.

Accessory agents are the antimuscarinecs (e.g. atropine, glycopyrrolate), which are useful in sedation and general anesthesia, and the neuromuscular blocking agents (e.g. curare, succinylcholine), which are useful only in general anesthesia.

The route of drug administration used in the dental office include oral, inhalation, submucosal, intramuscular, intravenous, and rectal. The selection of the route of administration and agents to be used depends on the dentist's expertise and experience and the ability to optimally accomplish the treatment plan. It is, however, the belief of the Board, that the dentist should utilize psychological approaches as much as possible to minimize drug dosage and thus ensure the safest levels of pharmacologic central nervous system depression. The Board further believes that careful attention must be given to the very young, the elderly, and the special patient. These considerations will ensure that management of each patient will be highly individualized.

4. <u>The risks associated with the use of general anesthesia, and conscious sedation.</u>

According to the National Institute of Dental Research, "reliable national estimates of mortality or morbidity associated with the use of general anesthesia and sedation in the dental office are not available for the United States. The most valid data, derived from a population-based study in Great Britain, indicate a mortality rate of 1 in every 250,000 general anesthetic administrations for the period of 1970-1979. Two large surveys of oral and maxillofacial surgeons in the United States suggest lower

estimates of risk, ranging from 1 in every 350,000 to 1 in every 860,000 general anesthetic administrations; however, the validity of these later estimates cannot be evaluated because of questions about the survey methods, completeness of data collect and the degrees to which the findings can be generalized. The British study indicates that treatment with local anesthesia with or without conscious sedation carries less risk than treatment with deep sedation or general anesthesia. Risks may increase in the medically compromised, the elderly, and the very young."

It is the Board's opinion that data concerning morbidity in the United States is extremely limited and does not permit the calculation of mortality rates. The Board does support the general impression that increased morbidity and mortality are associated with greater duration of anesthesia and complexity of the procedure. Confounding effects of medication being taken by the patient may also increase the risks associated with sedation and general anesthesia. A consultation with the patient's physician is usually advisable when the dentist is concerned about a patient taking medication.

Another important consideration in risk assessment relates to the choice and dosage of specific sedative and anesthetic agents. The use of any effective drug is almost always associated with some undesirable effects. For example, opiod drugs in therapeutic dosage cause respiratory depression and may cause airway obstruction. The use of central nervous system depressants for

conscious sedation, especially when used in combinations, requires careful titration and close monitoring to avoid unanticipated deep sedation or general anesthesia. For the medically compromised patient, the benefits of using sedation to relieve stress sometimes clearly outweigh the risk of aggravating the medical condition. A licensed dental professional, therefore, must have a thorough understanding about the effects drugs have on the cardiac, nervous and respiratory systems in order to administer these pharmacological agents properly and safely.

5. The facilities, equipment, personnel and training necessary for managing and monitoring dental patients.

The National Institute of Dental Research, along with the Food and Drug Administration and the National Institutes of Health's Office of Medical Applications of Research convened a Consensus Development Conference on Anesthesia and Sedation in the Dental Office on April 22-24, 1985. In their "Conference Statement," Volume 5, Number 10, they listed the following statements concerning what facilities, equipment, personnel, and training are needed for managing and monitoring dental patients under conscious sedation and general anesthesia:

a. Facilities and equipment. The effectiveness of all techniques used for control of pain and anxiety is significantly enhanced by a quiet environment. The facility should be properly equipped with suction and monitoring equipment, emergency drugs, and equipment capable of delivering oxygen under positive pressure. A protocol for management of emergencies should be developed, and

emergency drills should be carried out and documented.

b. Monitoring. For conscious sedation, the chart should contain documentation that heart rate, blood pressure, respiratory rate, and responsiveness of the patient were checked at specific intervals, including the recovery period. In addition, for deep sedation or general anesthesia, use of the precordial stethoscope for continuous monitoring of cardiac function and respiratory rate is a minimal requirement; an intravenous line, electrocardiographic monitoring or pulse oximetry, and temperature monitoring in children are desirable. Postoperative instructions and precautions should be discussed at the time that the preoperative consent is obtained and should be reinforced in printed form at the time of discharge.

c. Personnel. For conscious sedation, the practitioner responsible for treatment of the patient and/or administration of the drugs must be appropriately trained in the use of this modality. The minimum number of people involved should be two, i.e., the dentist or other licensed professional and an assistant trained to monitor appropriate physiologic parameters.

d. Training. Training for the use of conscious sedation techniques should conform to the American Dental Association's Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, Parts I and III. The didactic background and clinical experiences can be provided at the predoctoral, postdoctoral, and continuing education levels. The curriculum

should be sequenced to build on the basic science education, knowledge of physical evaluation, an understanding of psychological approaches, and the didactic material specific to each modality. The techniques should be taught to the level of clinical competence.

Training for deep sedation and general anesthesia requires a minimum of 1 year of advanced study or its equivalent as described in Part II of the American Dental Association's Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry. This training should have a dental orientation to assure the ability to apply the entire spectrum of pain and anxiety control to the needs of the dental patient.

The "Conference Statement", Volume 5, Number 10, concludes by stating, "The use of all effective drugs carries some degree of risk, however small. Available evidence suggest that use of sedative and anesthetic drugs in the dental office by appropriately trained professionals has a remarkable record of safety. However, even this record can be improved as scientific knowledge of dental anxiety and pain control is expanded, as strong training programs at all levels of professional education are developed, and as appropriate guidelines governing requirements for dental office personnel, facilities, and equipment are promulgated and adopted."

6. **The Minnesota Board Of Dentistry's Position.**

The increasing potency of newer drugs and the growing demand of the public have made the administration of pain control drugs a more complex circumstance. In other states, the failure to

regulate the standard of care required for competent administration of conscious sedation and general anesthetic agents has led to some morbidity and mortality. Such adverse occurrences has resulted in reactionary measures to control the standard of care which, in some cases, may have served to significantly restrict the availability of such anesthetic procedures. The State of New York, for example, in 1988 enacted a new law that prohibits a Dentist from administering general anesthesia or conscious sedation outside of a hospital setting without first obtaining a permit. In Maryland, a 1988 law authorizes the state dental board to require facilities in which dentists administer general anesthesia or conscious sedation to obtain a permit for that purpose.

In the State of Minnesota, no single episode of serious morbidity or mortality has been known to occur from the administration of general anesthesia or conscious sedation by dentists. It is therefore the position of the Board to recognize the need to act proactively by formulating rules that establish a high standard of care, without jeopardizing the quality of dental health care now existing in Minnesota. The authority to establish such rules was provided in 1984 by amendment of the Dental Practice Act, Minnesota Statutes Chapter 150A.04. This amendment specified that the Board my adopt rules for the education of persons who administer general anesthesia and conscious sedation in the dental office, over and above that educational level which is needed to receive a dental degree from an accredited dental school.

The Board believes that it is now prudent to enact such rules to ensure continuance of the high standard of care currently existing in the State of Minnesota and to ensure that the citizens of Minnesota are not placed in the position of waiting for a disaster to happen before the Board is permitted to regulate.

Prior to this time, the Board felt that Minnesota citizens were free from the threat of injury from poor quality health care due to the existing high standards of general anesthesia and conscious sedation practiced by dentists. The Board still believes that the quality of anesthesia and sedation practiced by dentists in Minnesota is high. However, it believes that the potential for injury to the people of Minnesota exists in the hands of unknown dental practitioners who may be untrained or ill equipped to provide general anesthesia and conscious sedation in response to the demands of the public. Therefore, it is now the Board's position that proactive rules should be put in place to ensure the general anesthesia and conscious sedation are administered only by licensees who are appropriately qualified, equipped, and trained. The Board has several options available for resolution of the problem:

1) The Board could restrict or disallow the use of general anesthesia or conscious sedation in any form altogether in the dental office. This would certainly eliminate the possibility or morbidity or mortality from any such practice; however, this measure would be reactionary since there have been no complaints or reports of morbidity and would therefore remove

quality pain control from a large portion of Minnesota citizens that require such pain control for effective treatment of their dental needs. Furthermore, such a harsh measure would force more persons into hospitalized circumstances for treatment of their dental conditions, which would have the net effect of increasing the cost of dental care tremendously, while limiting the availability of such care. The Board, therefore, rejects this option for the reasons stated.

2) The Board could enact strict guidelines that require anesthesiologists as M.D.s to be present during any out-patient general anesthetic, or require multiple doctor involvement in each case to be done involving general anesthesia or conscious sedation, as has been the case in a few other states, such as Colorado, Montana and Alaska. This has the effect of producing a different quality and character of general anesthesia/conscious sedation from that currently practiced in the state of Minnesota because the type of cases usually performed here are of short duration and on patients who are otherwise in good physical health. In addition, the availability of general anesthesia/conscious sedation to a patient as part of dental care, as well as the cost to the patient, would be adversely affected. The Board, therefore, rejects this approach.

3) The Board could enact such rules that would include on-

site inspection, oral and written examination of licensees, and specific requirements relative to equipment and paraphernalia for the site of the clinic of administration and for the licensee. However, this would require that the Board develop an evaluation committee that would regularly investigate licensees and their office of employment. Staff for such an evaluation team is not now available, nor is it provided for within the budget of the Board. Furthermore, successful performance in evaluation circumstances for such a committee would not ensure that licensees would conduct their dental practices in a manner consistent with high quality care in the absence of the evaluation committee. The equipment and paraphernalia required for compliance with current standards of care is constantly changing. Whatever the Board might determine to be satisfactory for current standards would likely be out of date within one or two years, requiring the total rewrite of such rules. The Board, therefore, rejects these suggestions as inadequate and unreasonable based on administrative complexity and associated costs.

4) The Board, however, believes that it is in the best interest of the public, for it to use its authority to place upon licensees the responsibility to maintain currency in both the education and equipment necessary to properly administer general anesthesia or conscious sedation in a dental office. The Board has the authority to require that licensees act to defend their compliance with the rules in the event of any

adverse occurrence or complaint filed with the Board. If the Board were to find that the licensee was in noncompliance, disciplinary action could ensue to require compliance, issue a "limited license," or remove the licensee from practice. The Board would enforce this system by reacting to individual situations, thereby ensuring the maintenance of the standard of care already in existence within Minnesota. The Board would not be required to investigate the educational qualifications and equipment preparedness of each licensee, so long as no adverse occurrences or complaints were received. By constructing the rules in this manner, the Board is in effect, putting every licensee on notice that if general anesthesia or conscious sedation is practiced by that licensee, certain standards of education and equipment preparedness are expected. The rules would also require completion of educational courses qualifying the dentist in advanced cardiac life support, which go beyond course work in basic life support. The Board, therefore, believes that this approach is the most necessary and reasonable according to the follow reasoning.

PART 3100.0100, DEFINITIONS, SUBPART. 8a. CONSCIOUS SEDATION, Subpart 12a. GENERAL ANESTHESIA, AND SUBPART. 15a. NITROUS OXIDE INHALATION ANALGESIA.

The proposed amendments provide definitions of the technical terms: "conscious sedation," "general anesthesia," and "nitrous oxide inhalation analgesia" in order to clarify their meaning as used in proposed part 3100.3600. These definitions follow closely those contained in the "Guidelines For Teaching the Comprehensive Control of Pain and Anxiety in Dentistry," published in 1985, by the American Dental Association's Council on Dental Education. As will be explained later in this document these guidelines were developed by the American Dental Association's Council on Dental Education and Commission on Accreditation. The American Dental Association's Commission on Accreditation has been recognized by the Board as the standard for educational matters in other Board Rules, as the Board is so empowered to do, in the Minnesota Dental Practice Act, Minnesota Statute Chapter 150A.

PART 3100.3600, TRAINING AND EDUCATIONAL REQUIREMENTS TO ADMINISTER ANESTHESIA AND SEDATION SUBPARTS, 1. PROHIBITIONS, 2.A. (1),(2),(3),B.C., GENERAL ANESTHESIA, 3.A. (1),(2) B.C., CONSCIOUS SEDATION, 4.A.B.C., NITROUS OXIDE INHALATION ANALGESIA, 5.A.B.C. NOTICE TO BOARD, 6. REPORTING OF INCIDENTS REQUIRED.

These proposed rules, specify the standard of education and training, equipment, and basic cardiac life support certification required for dentists who wish to administer pharmacological agents

for the purpose of general anesthesia, conscious sedation or nitrous oxide inhalation anesthesia, and, for dental hygienists who wish to administer nitrous oxide inhalation analgesia, in addition to the requirements of licensees to inform the Board of their intent to administer such pharmacological agents, the information and documentation required to be filed with the Board, and the reporting of incidents that arise as a result of licensees administering such pain control drugs. Without the establishment of the requirements and standards in these rules, the Board believes that it could not adequately regulate the administration of general anesthesia by the appropriate licensees in Minnesota. The Board believes that the only reasonable way to regulate these practices is to establish minimum educational and training requirements based upon the existing standards established by the American Dental Association's Council on Dental Education.

In November, 1985, the American Dental Association's Council on Dental Education published its "Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry." The American Dental Association stated in these Guidelines that, "Pain and anxiety control can be defined as the application of various physical, chemical and psychological modalities to the prevention and treatment of preoperative, operative and postoperative patient apprehension and pain. It involves all phases of dentistry and, as such, is one of the most important aspects of dental education." It further went on to state that, "These Guidelines are intended to delineate the scope of pain and anxiety control and to set

standards of acceptability for the teaching of this subject at the predoctoral, advanced (graduate and postgraduate) and continuing education levels. They present methods for achieving the objectives identified for each of these phases of instruction, with general descriptions of course content, sequence of instruction, faculty qualifications and suggestions regarding acceptable facilities and equipment. Prerequisites for admission to each level of training also are presented with emphasis, where indicated, between requirements for the general practitioner and the specialist. Finally, these Guidelines identify the kinds of institutions and agencies which should properly provide educational programs of pain and anxiety control."

In 1985, the National Institutes of Health (NIH) published a Consensus Development Conference Statement, Volume 5, Number 10, on "Anesthesia and Sedation in the Dental Office" based on the findings of the conference convened on April 22-24, 1985 by the National Institute of Dental Research of the NIH along with the Food and Drug Administration and the NIH Office of Medical Applications of Research. This Conference Statement specified that, "Training for the use of conscious sedation techniques should conform to the American Dental Association's 'Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, Parts I and III" and that, "Training for deep Sedation and General Anesthesia requires a minimum of one year of advanced study or its equivalent as described in Part II of the American Dental Association's 'Guidelines for Teaching the Comprehensive

Control of Pain and Anxiety in Dentistry."

In 1986, the American Dental Association published a "State Legislative Resource Packet on General Anesthesia and Conscious Sedation" containing the ADA's "Policy on the Use of Conscious Sedation, Deep Sedation and General Anesthesia in Dentistry" and the ADA's "Guidelines for Teaching the Comprehensive Control of Pain and Conscious Sedation." In this policy, the ADA states that, "Without effective pain control, many dental procedures such as endodontics, periodontal and oral surgery, and deep restorations, would be virtually impossible" and that, "Without effective anxiety control, many anxious patients would not seek needed dental treatment."

The ADA Policy further states that, "the use of conscious sedation, deep sedation and general anesthesia in dentistry is safe and effective when properly administered by trained individuals." The ADA Policy specified that, "training to competency in conscious sedation techniques may be acquired at the predoctoral or continuing education level. Dentists who wish to utilize conscious sedation are expected to successfully complete formal training which is structured in accordance with the Association's Educational Guidelines, Part One: Teaching the Comprehensive Control of Pain and Anxiety to the Dental Student and/or Part III: Teaching the Comprehensive Control of Pain and Anxiety in a Continuing Education Program."

The ADA Policy continues with the statement that, "the

knowledge and skills required for the administration of deep sedation and general anesthesia are beyond the scope of predoctoral and continuing education. Only dentists who have completed a minimum of one year in an advanced education program structured in accordance with Part Two: Teaching of Pain Control and Management of Related Complications at the Advanced Level of the Guidelines or equivalent advanced education are considered educationally qualified to use deep sedation and general anesthesia in practice." The ADA Policy and the Guidelines also identify that it is imperative that other interested medical groups such as the American Medical Association (AMA), the American Society of Anesthesiology (ASA) and the Joint Commission on Hospital Accreditation be contacted and involved in legislative efforts relating to the use of sedation and anesthesia by dentists and that their standards of treatment and currently accepted techniques be used in the development of state rules relating to the additional training and educational requirements for dentists using sedation and anesthesia. The Board believes that it is both necessary and reasonable to follow the course of the extensive research and efforts of the ADA in their "Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry" in the development of the proposed rule changes for the additional training and educational requirements for the administration of general anesthesia, conscious sedation, and nitrous oxide analgesia by Minnesota dentists.

D. Need For And Reasonableness Of The Proposed Rules For The Adequate Safety And Sanitary Conditions For Dental Offices And Infection Control.

PART 3100.6300, ADEQUATE SAFETY AND SANITARY CONDITIONS FOR DENTAL OFFICES, SUBPART 1., MINIMUM CONDITIONS.

The proposed change to this rule is simply of an editorial nature.

It reflects the addition of proposed subparts 12 and 13 to the part relating to adequate safety and sanitary conditions.

PART 3100.6300, SUBPART 11., INFECTION CONTROL.

The proposed amendment replaces the broad language in the current rules which require that "every dental office be equipped with adequate sterilizing facilities for instruments and supplies" and that "sterilization procedures shall be adequately and regularly employed;" with the more specific, "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures" contained in the United States Department of Health and Human Services, Public Health Service, Centers for Disease Control publication entitled, Morbidity and Mortality Weekly Report (MMWR), dated July 12, 1991, Volume 40, Number RR-8, pages 1 to 9. (Attachment A).

The above referenced Center For Disease Control publication shall be incorporated by reference into the rules pursuant to Minnesota Statutes section 14.07, subdivision 4. It has been

approved by the Revisor of Statutes pursuant to that section. When standards are being adopted by reference, the Board does not have to develop a point by point need and reasonableness justification for each item contained in the document which is being incorporated by reference. Instead the Board in this situation is only required to identify the problem which is being addressed and explain why it is reasonable for the Board to deal with the issue by adopting by reference the document in question. It is therefore the judgment of the Board that the adopting by reference the Centers for Disease Control's Recommended Infection Control Practices for Dentistry as the Minnesota Board of Dentistry's Standards for Infection Control is both necessary and reasonable as outlined in the following discourse:

a. <u>General nature of the problem in dentistry relating to the infection control problem.</u>

Infectious diseases are transmitted when improper or inadequate infectious controls are used. Improper or inadequate control means that the dental health care worker (dentist, dental hygienist, dental assistant) is not capable of providing an environment free of harmful biological elements through the use of proper sterilization, cleanliness, and equipment and supplies. Diseases are generally transmitted from the patient to dentist, dental hygienist, dental assistant, and to another patient in or on a medium capable of sustaining the harmful biological elements while in transit. These include, dental equipment, instruments, supplies, body fluids, etc.

Dental health care workers and dental patients are potentially exposed to a wide range of infectious agents from patients' blood and saliva. The common cold, influenza, pneumonia, herpes, tuberculosis, Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV), orally transmitted venereal diseases, and Acquired Immune Deficiency Syndrome (AIDS) are among conditions that can be transmitted by microorganisms from person to person.

In a 1985 Centers for Disease Control study, it was estimated that there were over 200,000 cases of HBV infection in the United States each year, leading to 10,000 hospitalizations, 250 deaths due to Fulminant Hepatitis, 4,000 deaths due to hepatitis-related cirrhosis, and 800 deaths due to hepatitis-related primary liver cancer. In a 1987 update, the Centers for Disease Control estimated the total number of HBV infections to be 300,000 per year with corresponding increases in numbers of hepatitis-related hospitalizations and deaths. The Hepatitis Branch of the Centers for Disease Control further estimated that 500-600 health care workers whose jobs entail exposure to blood are hospitalized annually, with over 200 deaths resulting. These studies also indicate that 10% to 40% of health care or dental workers may show serologic evidence of past or present HBV infection. When the Board couples this information along with a growing public concern over potential exposure to HBV, HIV, which causes AIDS, and other blood-borne diseases, it believes that there is a justified need to assure the public and dental health care workers of adequate barrier techniques and infection control procedures in the dental

office.

Dentistry has a long history of prevention and control of oral disease. There is an increased awareness of previously known diseases along with the recognition of escalating new disease conditions. Recent scientific literature, as well as reports from former U.S. Surgeon General, C. Everett Koop, have called for stringent infection control procedures, citing that transmittal and cross contamination can be prevented when such procedures are incorporated into dental offices.

In the fall of 1986, dentists in Minnesota were sent a survey, "Infection Control in the Dental Office", by the Minnesota Dental Association, with a 59% return response. At that time, 50% or less of dental health care workers had been immunized with the Hepatitis B vaccine. This is in spite of the fact that dental health care workers have a 5-10 fold greater chance of acquiring the infection than the general public. Relative to barrier techniques, ROUTINE GLOVE USE was reported to be: dentists, 33%, hygienists, 44%; and assistants, 33%; ROUTINE MASK USE: dentists, 28%; hygienists, 21%; and assistants, 18%; and ROUTINE GLASSES/GOGGLE USE: dentists, 60%; hygienists, 36% and assistants, 48%. Respondents indicated continuing efforts in the use of infection control. A similar survey in 1988 of Minnesota dental health care workers conducted by the Minnesota Department of Health in cooperation with the Minnesota Dental Assistants' Association and the Minnesota Dental Hygienists' Association (See Attachment B), did indicate a

significant increase in the use of infection control procedures, yet the Board believes that it is apparent that there is not universal adoption and compliance to such set standards by Minnesota dental health care workers and that the current Board rule is insufficient and that given the more recent findings about the potential spread of disease through the lack of proper infection control measures in dental practices that Minnesota needs to address the issue with the proposal of a more effective rule and standards.

b. Infection control in dentistry is a national problem.

The Board believes that it is both a legal and ethical responsibility for a dentist to provide appropriate training and safeguards for dental health care workers who may be exposed to these dangerous viruses and to protect dental patients. In April 1986, the Centers for Disease Control (CDC) of the U.S. Department of Health and Human Services published its "Recommended Infection Control Practices for Dentistry."

These guidelines of the U.S. Department of Health and Human Services have almost immediately become the nationally recognized standards for dental practice. In 1987, they were incorporated into the American Association of Dental Examiners "Guidelines for Infection Control and Disease Barrier Techniques in Clinical Examinations."

In October 1987, the Occupational Safety and Health Administration (OSHA), of the U.S. Department of Labor began a program to insure that health care providers were meeting the

need to protect their health care workers by responding to employee complaints and by conducting inspections of health care facilities to assure that appropriate measures are being followed.

On October 19, 1987, OSHA and the Centers for Disease Control published a Joint Advisory Notice entitled "Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)," which reflects many of the precautions addressed in the Centers for Disease Control Guidelines and includes other infection control procedures which should be considered. The Advisory stated that, "Engineering controls, work practices, and protective equipment appropriate to the task being performed are critical to minimize HBV and HIV exposure and to prevent infection. Adequate protection can be assured only if the appropriate controls and equipment are provided and all workers know the applicable work practices and how to properly use the required controls and protective equipment."

In November 1987, Ohio became one of the first states to mandate specific infection control procedures. When the Ohio State Dental Board enacted new Infection Control Rules that required Ohio dentists and dental health care workers who may be exposed to body fluids to show evidence of immunity to or inoculation against the Hepatitis B Virus. The rules also mandated that all dentists and dental health care workers wear disposable gloves, "whenever placing their fingers into the mouths of a patient" or "when handling blood or saliva contaminated items and masks and that

protective eyewear be worn in situations when the spattering of body fluids is likely". The Ohio Board also mandated the use of specific sterilization and disinfection procedures and procedures for the disposal of sharp items and contaminated waste. Other such states such as Florida, Tennessee, New Jersey, and Washington have recently followed suit with the adoption of similar Infection Control Rules.

The American Dental Association , in February 1988, published and sent to every dentist in the United States a guide, "Infection Control: Fact and Reality." This guide outlines the Centers for Disease Control's recommended standards and protocol for infection control in dental offices. In addition to this guide, an article was published in the JOURNAL OF THE AMERICAN DENTAL ASSOCIATION, Vol. 50, No. 7, 1986. In that statement, they "strongly recommended that the asepsis protocol include policy requiring the availability in use of gloves, masks and protective eyewear by faculty, staff, and students".

c. <u>The Minnesota Board of Dentistry's proposed approach to infection control.</u>

The Board believes that it is necessary and reasonable to establish specific infection control rules for Minnesota dental practices, in order to protect dental health care worker and patients from the risk of infection transmitted via bodily fluids during dental treatment. The Board recognizes, however, that it does not have the expertise or resources available to do the research that would be necessary in order to determine what the

standards should be with respect to infection control. Because infection control in dentistry is an on-going, evolving process, the Board believes that dental health care workers in Minnesota must be held responsible for keeping current with the latest appropriate techniques. On the other hand, the Board is aware that the Centers for Disease Control do have continuing access to national data and research relating to the transmission of disease as well as the expertise to interpret the data and research findings in a way which leads to the development of appropriate standards for infection control in dentistry. The Board also feels confident that the Centers for Disease Control is respected by national health care professionals for the quality of its work and that as reported previously, its recommendations are widely accepted by the American Dental Association and other dental professional organizations. It is therefore the Board's judgment, that the latest techniques for infection control, that Minnesota dental health care workers should be held accountable for being in compliance with, would be contained in the Recommended Infection Control Practices for Dentistry, of the Centers for Disease Control. The Board therefore believes that it is both necessary and reasonable to hold Minnesota's dental health care workers, accountable to be in compliance with infection control techniques specified in the Centers for Disease Control Standards.

Although it has been argued by Minnesota dentists in the Board's public forums that there is no current documentation of patient-to-patient blood or saliva-borne disease transmission from

procedures performed in dental practice, the Board believes that the occurrence of a number of reported outbreaks of dentist-to-patient transmission of Hepatitis B (that have resulted in serious and even fatal consequences) and the fact that the herpes simplex virus has been transmitted to over twenty patients from the fingers of dental health care workers in the U.S.; strongly suggests that current infection control practices have been insufficient to prevent the transmission of infectious agents in dental operatories and that requiring dental practices to adhere to the infection control standards and procedures recommended by the Centers for Disease Control should be effective in preventing the transmission of infectious agents from Minnesota dental patients to Minnesota dental health care workers and vice versa.

PART 3100.6300, SUBPART 12, SHARP ITEMS AND CONTAMINATED WASTES

This proposed amendment further adds to the requirements for infection control, that all sharp items and contaminated wastes must be disposed of in accordance to Minnesota Statutes, sections 116.76 to 116.83, and the rules adopted under them, and requirements established by local environmental agencies. It recognizes the well documented fact that all sharp items, (especially needles), tissues, or blood should be considered potentially infective and should be handled and disposed of with special precautions. The current Minnesota Pollution Control Agency requirements and many local environmental agency

requirements currently require that disposable needles, scalpels, or other sharp items should be placed intact into puncture-resistant containers before disposal and that blood, suctioned fluids, or other liquid waste must be carefully poured into a drain connected to a sanitary sewer system. They also require that other solid waste contaminated with blood or other body fluids be placed in sealed, sturdy, impervious bags to prevent leakage of the contained items before such contained solid wastes are properly disposed of. The Board believes that it is necessary and reasonable to adopt by reference into its rules these sections, and the rules adopted under them, along with the requirements established by local environmental agencies, because to establish different standards for dentists and dental practices would only cause confusion among dentists and the public and therefore likely create further problems. In addition, the Board recognizes that the Minnesota Legislature has seen fit to delegate the regulation of the disposal of sharp items and contaminated wastes to the Minnesota Pollution Control Agency and the Board therefore finds no reason to interpose itself into this regulation process.

The Board, however, does recognize that dental offices, operatories, labs, etc.; are generators of infectious waste. The Board further recognizes that the failure of a licensee or registrant to comply with all statutes and/or rules relating to infectious waste, could pose a health risk to the public whether the public is a patient, dental health care worker, employee, or other individual involved in the creation or disposal of such

waste. The Board therefore believes that it is necessary and reasonable in the interests of the public safety and welfare to require a licensee or registrant to comply with all statutes and/or rules relating to infectious waste and that failure to comply should be grounds for the Board to take specific disciplinary actions to ensure compliance. The Board believes that although the Minnesota Pollution Control Agency may be actively involved in pursuing such matters, that it does so primarily from a concern about proper waste disposal rather than the conduct of the dental licensee or registrant, which is the area that the Board can closely regulate.

PART 3100.6300, Subpart 13, BASIC LIFE SUPPORT.

This proposed amendment to the rules, adds the very necessary requirement that at least one dental health care worker, with a current certification in basic life support approved by the American Heart Association, the American Red Cross, or an equivalent agency, be present in the dental office when dental services are performed. The Board believes that this proposed rule change is both necessary and reasonable so that dental patients will be assured that dental health care workers are current in the latest survival techniques. The Board is concerned that the administration of anesthesia and chemotherapeutic drugs in dental treatment can produce respiratory embarrassment and heart failure. The Board is also further aware that as patients become older, the debilitated and medically compromised patients may need immediate

cardiopulmonary resuscitation (CPR) at the dental treatment site, instead of waiting for emergency services from medical personnel. The Board believes, therefore, that the requirement that a minimum of one dental health care worker that is in possession of a current certification in basic life support be present in the dental office when dental services are provided is both necessary and reasonable in order to protect the public safety and interest. This appears to be the most reasonable approach for the Board to employ in protecting the public welfare, instead of requiring that all dental health care workers maintain possession of a current certification in basic life support as a basis for licensure and registration renewal. This not only eliminates an enormous amount of administrative work and expense, on the part of the Board, but it properly lays the responsibility for the protection of the dental patient in the hands of the dental health care workers, where it legally and ethically belongs.

E. <u>The Need For And Reasonableness Of Amending The Permissible Duties of Registered Dental Assistants and Dental Hygienists and the Required Level of Supervision.</u>

The Board believes that the following historical summary pertaining to dental auxiliary duties in Minnesota is helpful in explaining why it is the judgment of the Board that the proposed rule changes are needed and reasonable. Minnesota Statute 150, initially governed the permissible duties for dental hygienists until it was repealed in 1969 by Minnesota Statute 150A. At this time, the permissible duties of dental assistants were first

defined under Minnesota Statute 150A.10 Dental Auxiliaries, Subpart 1, Dental Hygienists, Subpart 2, Dental Assistants, which stated that dental assistants were permitted to do all of those acts which a dentist was permitted to delegate to the dental assistant by the Board of Dentistry.

The dental assistants' duties were left unchanged until April 13, 1976 when the category, Registered Dental Assistant (R.D.A.), was added with this group given the authority to perform specified expanded duties. On October 26, 1976, the monitoring of nitrous oxide was added to these duties. Some minor revisions in the R.D.A.'s duties were made in March 1981.

During the process that changed the rules governing R.D.A.'s duties in 1981, there had been discussion to add expanded functions but the Rules Committee and then the Board decided not to pursue changes that would add functions. Also during the same period, a strong effort was made to eliminate the monitoring of nitrous oxide by R.D.A.'s, however, the Board decided against this because it was deemed that the rule was unenforceable. The Board determined that if a dentist did not have an R.D.A. or dental hygienist to carry out the function of monitoring nitrous oxide, they could have no one do it and still be operating within the letter of the rules/law. After considerable debate, it was decided to leave the rule as it was. After the last series of rule changes by the Board of Dentistry in March 1981, at which time no changes were made in expanded functions, the Rules Committee discussed looking at possible additions and deletions in the permissible duties of both

dental hygienists and dental assistants, in response to receiving a number of requests for changes from many dental professional organizations, including the Minnesota Dental Association, the Minnesota Orthodontists Association, the Minnesota Dental Hygienists' Association, the Minnesota Dental Assistants' Association, and the Minnesota Educators of Dental Assistants. The Rules Committee at this time requested input from all interested parties as to what changes should be made and during the 1980's two public forums were conducted by the Board on June 25, 1988 and July 26, 1988.

In the 1980's, the expanded duties for R.D.A.s and dental hygienists have been discussed at great length by the Rules Committee of the Board, much input has been received from interested parties as to their need and reasonableness, and it was only after these discussions that the proposed rule changes for permissible duties were prepared. The Board believes that the proposed rules will provide R.D.A.s and dental hygienists the opportunity to more clearly identify whether they wish to take additional training in certain advanced functions. Finally, the additional educational training required, will permit R.D.A.s and dental hygienists to legally perform duties that they are currently being requested to do by practicing dentists. The Board has clearly stated its position over the years of not expanding the permissible functions for dental auxiliaries unless it could be assured that such functions could and would be taught in dental

auxiliary programs. It has therefore, worked very closely with dental auxiliary educators, including, Ms. Kathy Lapham, a member of the Board from 1982 to 1990.

An example of this concern by the Board has been its response to the request by dentists practicing orthodontics, their allied dental auxiliaries, and their respective professional organizations to expand the permissible duties of R.D.A.'s and dental hygienists as they relate to orthodontic procedures and their required level of supervision. It was presented to the Board, that due to the development of new dental materials and procedures, that orthodontists believed that they could make better use of dental auxiliaries and treat patients more effectively , if their permissible functions were expanded. The Board then responded by agreeing to expand the functions once the Board was satisfied that the educational opportunities were truly there for the dental auxiliaries to learn the functions and that such expansion of duties would not be harmful to the public and was in fact, in the public's best interests. The Board feels justified in proposing these new permissible duties after a great deal of communication and discourse with the Minnesota Dental Association, the Minnesota Orthodontists Association, the Minnesota Dental Hygienists' Association, the Minnesota Dental Assistants' Association, and the Minnesota Educators of Dental Assistant, who have all endorsed the proposed rule changes in recent letters to the Board.

The adoption of these proposed rule changes should also provide a more clear understanding on the part of dental

auxiliaries and dentists and the public as to the level of supervision required for each of the permissible duties performed by R.D.A.s and dental hygienists because they clearly specify and define the level; indirect, direct, or general, that the permissible duties are to be performed under. Indirect supervision specifies that the permissible duties may only be performed, "if the dentist is in the office, authorizes the procedures, and remains in the office while the procedures are being performed." Direct supervision specifies that the permissible duties may only be performed, "if the dentist is in the dental office, personally diagnoses the condition to be treated, personally authorizes the procedures, and evaluates the performance of the auxiliary before dismissing the patient." General supervision specifies that the permissible duties may be performed if, "the dentist has authorized them and the hygienist carries them out in accordance with the dentist's diagnosis and treatment plan". The Board believes that it is justified in defining the level of supervision that must be provided by the dentist in order to safeguard the public interest because of the substantial number of complaints and problems that it has received from the general public over the last several years, particularly as they relate to the practices of orthodontists and the use of their R.D.A.'s and dental hygienists.

In conclusion, the dental profession in Minnesota and nationally has progressed from the use of Dental Hygienists in a

very limited role to adding dental assistants, then registered dental assistants, and along the line increasing the functions which the various auxiliaries could perform, once there was assurance that proper educational and training programs were available, the proper level of supervision was provided, and that such expansion would not be harmful to the public. It is therefore, the belief of the Board, that the proposed rule changes are simply another step in the recognition by the Board of the growing role in the dental profession and dental treatment of dental auxiliaries and that such proposed rule changes are necessary and reasonable.

It is, as stated previously, the Board's judgment that the proposed rule changes for the permissible duties of registered dental assistants and dental hygienists, and their required level of supervision by the dentist, that are addressed herein, more clearly delineate the provisions of the Minnesota Dental Practices Act, for the purpose of safeguarding the public welfare and promoting the best interests of the dental profession and that they have a rational basis in both law and dentistry as detailed below.

PART 3100.8500, SUBPART 1. REGISTERED DENTAL ASSISTANTS.

The proposed amendment deletes the phrase "Indirect Supervision" from the description of permissible duties of R.D.A.'s and inserts instead, the definition of and key elements of indirect supervision. The proposed change is only an editorial one, which

is designed to aid in the reading and understanding of the rules by both the public and dental professionals.

PART 3100.8500, SUBPART 1 B.

The proposed amendment replaces the former language of "take impressions for study casts and opposing casts" with "take irreversible hydrocolloid impressions and waxbites for study, opposing models, and orthodontic working models." The Board believes that it is reasonable to delegate to substitute this language since it specifies the precise type of impressions that R.D.A.'s are permitted to take instead of the more general statement of "take impressions" and also delineates the specific purposes permitted for taking irreversible hydrocolloid impressions and waxbites.

PART 3100.8500, SUBPART 1 C.

The proposed amendment deleting the prohibition of R.D.A.'s from performing pit and fissure sealants is necessary because the function is now being permitted under the proposed rule change in Part 3100.8500, Subpart 1.a.D.

PART 3100.8500, SUBPART 1 F.

This proposed amendment is editorial in nature only.

PART 3100.8500, SUBPART 1 H.

The proposed amendment is necessary because the function of R.D.A.'s removing and replacing ligature ties on orthodontic appliances is being moved to Part 3100.8500, Subpart 1.a.B. The change then reorders Subpart 1 I to H.

PART 3100.8500, SUBPART 1 J.

The proposed amendment merely restates what the old rule stated in a more accurate manner by replacing the words, "monitor a patient who has been, inducted by a dentist into nitrous oxide oxygen relative analgesia" with, "monitor a patient who has been induced by a dentist into nitrous oxide inhalation analgesia; and"

PART 3100.8500, SUBPART 1 K.

The proposed amendment places the function to "place and remove orthodontic separators" under the permissible duties of R.D.A.'s. The addition of this function to the permissible duties of R.D.A.'s was proposed to the Board by the Minnesota Dental Assistants' Association, the Minnesota Dental Hygienists Association, and the Minnesota Dental Association, because it is an orthodontic procedure where there is little or no additional patient risk, due to the fact that it is a non-evasive procedure that is reversible upon removal of the separators. The patient is protected in several ways including: the dentist must authorize the procedure and must remain in the dental office while the duty is performed; the R.D.A. is required to be educated and trained to clinical competency in this particular procedure in a Dental Assisting Program recognized and accredited by the American Dental Association Commission on Accreditation and approved by the Board(Attachment C); and the dental experts and professionals in orthodontics have recommended that R.D.A.'s perform this duty, formerly only performed by dentists for the above reasons, in addition to the fact that, the patient benefits from R.D.A.'s

performing this function because it frees the dentist to concentrate efforts on performing other more invasive procedures, therefore promoting more schedule flexibility.

PART 3100.8500, SUBPARTS 1 a, A, B and C.

The amendment proposes that the orthodontic procedures of A."remove excess bond material from orthodontic appliances with hand instruments only"; B."remove and replace ligature ties on orthodontic appliances"; and C. "etch appropriate enamel surfaces before bonding on orthodontic appliances by a dentist", be added to the permissible duties of R.D.A.'s under the direct supervision of a dentist, which requires that the dentist is present in the dental office, personally diagnosis the condition to be treated, personally authorizes the procedure, and evaluates the performance of the auxiliary before dismissing the patient. The Board believes that it is necessary and reasonable to include these orthodontic procedures in the permissible duties of R.D.A.'s under the direct supervision based upon numerous inquiries it has received over the last several years from the public, relating to their concerns about orthodontic treatment that includes functions delegated to dental auxiliaries and after its review of recommendations received from the Minnesota Association of Orthodontists and the Minnesota Educators of Dental Assistants.

SUBPART 1a A. Remove Excess Bond Material From Orthodontic Appliances With Hand Instruments Only

The removal of bonding materials, with hand instruments only, on an appropriately etched surface requires no additional skill or

training beyond that required for the function of the removal of excess cement as identified in Minnesota Rules Part 3100.8500, subpart 1,E., which is listed under Indirect Supervision. The removal of excess cement with hand instruments only, has been a permissible duty for R.D.A.'s for more than 13 years. The risk to the patient is minimized in that the R.D.A. is only permitted to use hand instruments. If the excess bond material cannot be easily removed with hand instruments, a rotary instrument (i.e. a dental drill) would more than likely be required. This determination can only be made by a dentist. Therefore the Board believes that it is reasonable that this duty should only be performed under the direct supervision of the dentist, in order to ensure proper patient protection. The Board believes that the dentist needs to personally evaluate the patient, because hard material, such as bond material, should be removed before the patient is dismissed. Newer materials are being used in orthodontic procedures to bond brackets onto teeth, rather than cementing brackets into place. The Board believes that the addition of this permissible duty for R.D.A.'s, in light of a previously authorized similar duty, is both necessary and reasonable to the public interest, under the level of direct supervision.

SUBPART 1a B. Remove and Replace Ligature Ties on Orthodontic Appliances

Placing and removing ligature ties on orthodontic appliances by R.D.A.'s was permitted under Minnesota Rules part 3100.8500, subpart 1 H, promulgated by the Board in 1979. It was reasoned at

that time, by the Board, that these duties were not considered to be evasive and that adequate control could be exercised by the dentist under indirect supervision. Based on information it received from the public during the 1980's, the Board has determined that the public interest would be better served by moving this duty to direct supervision by the dentist. Under direct supervision, the dentist is required to check and evaluate the performance of the R.D.A. in placing and removing ligature ties on orthodontic appliances, before the patient is dismissed.

SUBPART 1a C. Etch Appropriate Enamel Surfaces Before Bonding on Orthodontic Appliances By a Dentist

The etching of appropriate tooth enamel surfaces before the bonding of orthodontic appliances by the dentist is a new permissible duty for R.D.A.'s being proposed by the Board. The special expertise in the bonding process is not the etching of appropriate tooth surfaces, but rather the placing of the bonds and brackets. Only a dentist is permitted by law, to place orthodontic appliances. The Board, however, believes that it is reasonable to permit R.D.A.'s to perform the etching of appropriate tooth enamel surfaces before the bonding of orthodontic appliances under direct supervision, since the dentist would be required to personally authorize the procedure and evaluate the performance of the R.D.A. before personally bonding the orthodontic appliance and then dismissing the patient. This would also permit the dentist to ensure that the procedure has been performed adequately prior to bonding. Reasonably permitting this R.D.A. duty as part of the procedure, the Board believes is reasonable to permit dentists to devote their time and expertise to more important issues of patient care, thus providing, hopefully, for more expedient care and cost containment, thereby permitting services to be enjoyed by a larger number of patients.

PART 3100.8500, SUBPART 1a D.

This amendment proposed that R.D.A.'s be permitted to perform the procedures of etching appropriate enamel surfaces and then applying pit and fissure sealants under the direct supervision of a

dentist. These permissible duties could only be performed by R.D.A.'s, however, who have successfully completed a course in pit and fissure sealants at a dental school, dental hygiene school, or dental assisting school that has been accredited by the Commission of Accreditation of the American Dental Association and includes a minimum of eight hours didactic instruction and supervised preclinical or clinical experience. The procedures of etching appropriate enamel surfaces and then applying pit and fissure sealants are conceptually uncomplicated. The tooth must first be isolated so that adequate access is established to observe the field and to reach the tooth surfaces with the appropriate instruments. The surfaces should then be cleaned with a prophylaxis brush or rubber cup and a cleansing agent. The cleaning agent is then carefully washed from the surfaces using a water syringe and aspiration or high speed evacuation. When the teeth are effectively isolated from saliva contamination, the surfaces are dried and etched by the application of a 30 to 50 percent phosphoric acid solution for one minute. The solution is gently agitated during the application to ensure it covers all of the areas to be sealed. The acid is then washed away with water and aspiration or high speed evacuation. The surfaces are carefully dried and inspected to ensure that the frosty appearing etch covers the area intended, while avoiding the contamination with saliva, air-line moisture, or oil. The sealant is then applied, with care taken to avoid entrapment of air bubbles, to extend the sealant into all grooves and pits, and to avoid

extension of the sealant onto unetched smooth surfaced or soft tissue. The sealant must remain uncontaminated and undisturbed until it is cured to hardness. The sealant is then examined to ensure that underextension, overextension, undercurving, or voids have not occurred.

In the 1984, JOURNAL OF DENTAL EDUCATION, Vol.48, No.2 (Attachment D) it was reported that, "it is generally agreed that the use of pit and fissure sealants in clinical practice is not widespread or commensurate with its proven value as a caries-preventive procedure. Many experts believe that dental auxiliaries should be viewed as a greater resource than practicing dentists for increasing the use of pit and fissure sealants and perhaps, a more effective one."

At the present time approximately 35 states allow dental hygienists to place sealants and approximately 14 states allow dental assistants to place sealants. Research studies demonstrate that sealants can be successfully applied by dental auxiliaries and many investigators and practitioners feel that this duty can be delegated to adequately trained auxiliaries. In a recommendation published by the American Dental Association , it was stated that the procedure of placement of pit and fissure sealants is considered safe when used by properly (maximally) trained auxiliary personnel under the direct supervision of a dentist. The delegation of the procedure represents no more of a threat to the integrity of dental practice than the delegation of other primary preventive procedures."(Attachment D)

The recognition of the American Dental Association's Commission on Accreditation as the organization that the Board must rely on with respect to educational achievement relating to licensure is and has been recognized in Minnesota Rules part 3100.0100, subpart 8. In its 1980 "Accreditation Standards for Dental Assisting Education Program", the Commission on Accreditation specifies in Standard Number 11, the criteria that must be met and maintained by any dental assisting educational program teaching expanded functions and desiring accreditation by the A.D.A. These include ensuring that the student attain clinical competence in performing such function, with appropriate instruction in the relationship of the advanced function component to the total dental procedure and the legal and ethical responsibility of the dental assistant. Methods of instruction must assure that students achieve laboratory competence prior to initiating clinical practice with patients and that the students be given appropriate clinical experience in performing such expanded function necessary to achieve an acceptable level of competency. It is the Board's educated opinion after consulting with a number of experts that eight hours of didactic instruction and supervised preclinical or clinical experience would be the minimum of training necessary to fulfill the above mentioned A.D.A. accreditation standard.

The Board, therefore, believes that it is necessary and reasonable in order to promote the use of pit and fissure sealants and still protect the public interest, to permit appropriately

trained R.D.A.'s to etch appropriate enamel surfaces and apply pit and fissure sealants, under the direct supervision of a dentist.

PART 3100.8500, SUBPART 1a E.

This proposed amendment permits R.D.A.'s to make preliminary adaptation of temporary crowns under the direct supervision of a dentist. When teeth have been prepared for crowns, there is usually a waiting period of a week or so while the permanent restoration is being prepared in a dental laboratory before it can be placed in the patient's mouth. During this period, the use of temporary crowns to protect the prepared teeth and gingival tissues are employed. Another important function of temporary crowns is to occupy space in the dental arch to prevent shifting of teeth. In preparing teeth to receive a crown, the material removed, creates a space in the dental arch. This alters the balance of forces acting on the adjacent teeth so that they may tend to migrate laterally into the space. The temporary crown prevents this migration.

The function of making the preliminary adaptation of a temporary crown involves: 1) the selection of a temporary metal crown that is just small enough to fit snugly between the adjacent teeth and yet large enough to slip over the neck of the prepared tooth and rest on the shoulder of the preparation; 2) the fitting of the crown down onto the shoulder of the preparation and the estimation of how much farther it will need to go to be level with the adjacent teeth 3) the trimming of the crown, with a scissors or other instrument, until such time as the patient can bring the adjacent teeth into contact without displacing the crown and the

opposing teeth can meet, without forcing the crown down past the margin of the preparation.

The Board believes that this is a non-evasive procedure that can be safely and properly performed by R.D.A.'s under direct supervision, prior to the dentist performing the next function of evaluating the fit of the temporary crown and making the necessary adjustments prior to cementing the temporary crown. Permitting this expanded R.D.A. duty under direct supervision, the Board believes does not compromise the safety of the patient in any manner, but does again serve to free the dentist to perform other more appropriate procedures while the R.D.A. is making the preliminary adaptation of the temporary crown.

PART 3100.8700, SUBPART 1. DENTAL HYGIENISTS.

Duties Under general supervision. This proposed amendment merely makes an editorial change by removing the term "general supervision" and instead inserting the definition of general supervision, which already exists in the definition section of the rules, but which the Board believes will be helpful in making the rules more understandable to the public and to dental professionals.

PART 3100.8700, SUBPART 2.

This proposed amendment merely makes an editorial change by removing the term "under the indirect supervision of a licensed dentist" and instead ensuring the definition of indirect supervision, which already exists in the definition section of the rules, but which the Board believes will be helpful in making the

rules more understandable to the public and to dental professionals.

PART 3100.8700, SUBPART 2 A.

The amendment proposes the listing of "remove marginal overhangs", under the permissible duties of dental hygienists under indirect supervision, instead of including it in the body of subpart 2, as it currently exists. This is merely on editorial change.

PART 3100.8700, SUBPART 2 B.

The amendment proposes that dental hygienists be permitted, under the indirect supervision of a dentist, to induce into nitrous oxide inhalation analgesia a patient who has been prescribed its use by a dentist, only for the purpose of alleviating pain for dental hygiene procedures. It further provides that the hygienist has not the educational requirements in Part 3100.3600, subpart 4, i.e., "only after satisfactorily completing a dental school, postdental graduate, dental hygiene, or postdental hygiene education course from an institution accredited by the Commission of Accreditation, that includes a minimum of 16 hours of didactic instruction and supervised clinical experience using fail-safe anesthesia equipment capable of positive pressure respiration". The dental hygienist "must also have successfully completed and be currently certified in basic cardiac life support as provided in educational programs recognized by the American Heart Association, the American Red Cross, or other similar agencies." Under part 3100.3600, subpart 5, item C., beginning January 1, 1992, a dental hygienist who wishes to administer nitrous oxide inhalation analgesia, is also

required to provide the Board evidence of the satisfactory completion of a training program in nitrous oxide inhalation analgesia that complies with requirements of subpart 4, item A., in addition to a statement that the licensee is currently certified in basic cardiac life support as required by subpart 4, item B. The justification for these requirements is found in Section IV C above.

Nitrous oxide is a mild inhalation anesthetic gas which has anxiolytic actions as well as analgesic properties. It produces a physiologic effect on the transmission of pain stimuli and a psychological effect on the perception of pain, both without the loss of consciousness. The Board agrees with the current dental research that indicates that the use of nitrous oxide and oxygen during dental procedures benefits both the patients and the dental hygienist and dentist as well. It is estimated that 50% of the population in the United States do not seek dental care, with the fear and anxiety associated with dental care cited as a major factor. Pain control is often necessary for the safe and comfortable performance of routine dental care. The state of relative analgesia induced by nitrous oxide and oxygen results in a calm and relaxed patient whose sensitivity to pain is greatly reduced. The Board believes that this increased tolerance for dental procedures, such as subgingival instrumentation and scaling, will enhance the dental hygienist's ability to provide quality treatment to the anxious patient and will in some cases, circumvent the need to interrupt the dentist to request a local anesthetic

agent. Ultimately, the Board believes, reducing the fear and discomfort associated with dental visits, has the potential to encourage more individuals to seek dental care, while posing a minimal and manageable risk to the public welfare.

The administration of nitrous oxide is quite simple for a well- trained dental hygienist. The first task is to explain to the patient what the nitrous oxide will do. Because nitrous oxide causes a euphoria, it is important that the patient has some idea what to expect. This can be that the patient will feel relaxed, have a floating sensation, feel warm or have a tingling in the arms or legs, feel a numbness or feel nothing at all. The reaction to nitrous oxide is different for each individual. The dental hygienist then places the inhaler in the patient's mouth and turns on the mixture of nitrous oxide and oxygen. The patient is then told what they are breathing, while the hygienist makes sure there is enough gas in the mixing bag for the patient to breathe. Most people breathe at the rate of six liters per minute. This means that five-six liters per minute of gas should flow through the mixing bag. At some time before dental treatment is completed for the patient under nitrous oxide, the nitrous oxide is shut off and the patient breathes oxygen only. This allows the nitrous oxide to be lost from the body while assuring the patient an adequate supply of oxygen. If the switch from nitrous oxide and oxygen to straight oxygen is made early enough in the treatment procedure, the patient should not feel the effects of the nitrous oxide when treatment is completed. At any rate the patient should

breathe straight oxygen for a minimum of three minutes following the use of nitrous oxide. The dental hygienist then monitors the patient to ensure that the nitrous oxide has worn off and the patient should not be dismissed until the patient feels in complete control of all faculties.

Dr. Stanley F. Malamed an Associate Professor of Anesthesia and Medicine for the University of Southern California School of Dentistry, wrote in his January 21, 1988 letter to the Board that "the technique of nitrous oxide inhalation analgesia has been successfully used in dentistry for over one hundred years. Through its use the dentist and dental hygienist are able to safely and effectively decrease anxiety toward dental treatment as well as elevating the patient's pain reaction threshold. These goals are achieved in a patient who remains fully conscious (alert and awoke) throughout the procedure. In addition the technique of inhalation sedation is the single most controllable technique of sedation available in medicine and dentistry today. The induction of the sedative state occurs rapidly permitting the administrator to titrate each patient to the appropriate level of sedation required for their treatment. It is the technique of titration which lends a degree of safety to the use of nitrous oxide which is not found in any other technique of sedation. Additionally inhalation sedation is the only technique in which the sedative agents can be removed from the patient, permitting essentially complete recovery in virtually all patients. Within 30 seconds after decreasing the flow of nitrous oxide, or by increasing the flow of oxygen, a

visible lessening of sedation will be observed in the patient. The operator maintains a significantly greater degree of control over this technique than any other sedative technique currently available."

Dr. Malamed continues in his letter to state, "add to this inherent safety the additionally safety features of the inhalation sedation units currently available. The American Dental Association Council on Dental Materials, Instruments, and Devices has certification guidelines for inhalation sedation units. Included in these guidelines are safety features which must be present if a device is to be deemed acceptable to the ADA. A few of these safety features are: the pin index safety system: diameter index safety system; color-coding; minimum oxygen flow rate; minimum oxygen percentage; and oxygen fail safe devices and alarms. The primary function of all of these devices is to prevent the patient from ever receiving a mixture of gases in which the concentration of oxygen is less than atmospheric (21%). Indeed with the technique of inhalation sedation being taught at the current time, the typical dental patient middle of the bell-shaped curve will require but 30% to 40% nitrous oxide to achieve adequate sedation. The patient is therefore receiving between 60% and 70% oxygen, about three times normal oxygen concentration."

"Permitting the dental hygienist to receive the same training as the dental student or dentist in this subject (including clinical experience under supervision) has provided the dental profession with a significant number of dental hygienists who have

an added means of helping their patients to cope with their fears of dentistry. These courses should include both didactic and clinical experience under supervision and include written and clinical examinations leading to certification in this area."

"The safety of this technique is unparalled. There is none safer. Add to this, well conceived training courses in inhalation sedation and the patients of Minnesota dentists and hygienists will be the beneficiaries of a higher level of dental care without an added degree of risk."

"I support without hesitation, the request of the Minnesota Dental Hygienist Association to permit the administration of nitrous oxide and oxygen inhalation sedation to dental patients by well-trained, certified, dental hygienist."

The Board believes that this proposed rule change is both necessary and reasonable because the state of the art in today's dental practices, makes the administration of nitrous oxide inhalation analgesia by dental hygienists a positive adjunct to the care of patients and an enhancement to dental hygiene treatment. Some states have permitted dental hygienists to administer local anesthetics for the past ten years. The Board looked at this issue twice over the last ten years and did not take action. The practice of dentistry, however, has changed considerably and the safeguards designed into equipment have improved and the reactions to analgesia by patients have reduced significantly. The Board now believes that it is justified and reasonable to permit trained dental hygienists, under the indirect supervision of a dentist to

induce into nitrous oxide inhalation analgesia a patient who has been prescribed its use by a dentist, only for the purpose of alleviating pain for dental hygiene procedures.

PART 3100.8700, SUBPART 2a.

The proposed amendment gives dental hygienists the right to perform essentially the same functions as are delegated to R.D.A.'s under the proposed Rules, Part 3100.8500, Subpart 1.A., with a few variations. The variations are that R.D.A.'s may remove "excess" bond material, while the wording for the dental hygienists is simply that they may remove bond material. The Board believes that this distinction is necessary and reasonable.

ATTACHMENTS

A. Centers For Disease Control, Morbidity And Mortality Weekly Report, July 12, 1991, Vol. 40, No. RR-8, Pages 1-9.

B. Minnesota Department of Health, Infectious Disease Control Survey, August-September, 1988.

C. American Dental Association Commission on Dental Accreditation, "Accreditation Standards for Dental Assisting Education Programs", Copyright 1980.

D. Journal of Dental Education, Vol.48, No.2 1984.