RADIATION SAFETY PROGRAM GUIDE
For the Nomad Pro Handheld X-ray System for Intraoral
Radiographic Imaging

University of North Carolina School of Dentistry Clinics

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INTRODUCTION

The North Carolina Division of Radiation Protection enforces the radiation rules in North Carolina. These rules require that radiation machines meet specific requirements. The rules also require that certain procedures be at the UNC School of Dentistry:
- Letter acknowledging exemption from the Radiation Protection Section regarding the Nomad Pro Handheld X-Ray System for Intraoral Imaging.
- Notice of registration
- A copy of the North Carolina Regulations for Protection against Radiation (NCRFPAR). The regulations can also found at the following Web address: www.ncradiation.net
- Notice to students using the system
- Written Safety Procedures
- Form FDA 2579 (this comes from the manufacturer Aribex)

The procedures in this document are intended to minimize radiation exposure to x-ray personnel and patients when the Nomad Pro Handheld X-Ray System is used. You (the operator) are required to know the procedures and requirements outlined in this document and complete the Nomad Pro Handheld operator’s training. A test score of 100% percent is required after you complete the Nomad Pro Handheld operator’s training before you can operate the device. In addition, after reading this Radiation Safety Program Guide you must sign and date the record that you have read and understand the Radiation Safety Program Guide for the Nomad Pro. (Appendix A)

RSO
Dr. Donald Tyndall is the Radiation Safety Officer (RSO) and has the responsibility and authority for overseeing matters relating to radiation protection and use of Nomad Pro Handheld X-Ray System for Intraoral Radiographic Imaging. The RSO also confirms all training and serves as the contact person with the state. Employees should submit all radiation questions or concerns about radiation safety to the RSO.

PERSONNEL TRAINING
In compliance with section .0603 General Requirements:
Persons employed who will be expected to expose radiographic images will:

1. Complete operator training of the Nomad Pro Handheld X-Ray System for Intraoral Radiographic Imaging and attain a 100% score on the test before begin its use. The user must show proficiency in its operation including
   a. location of power switch
   b. location and use of exposure controls
   c. location of technique charts
   d. location and storage of charger
   . f. infection control procedures established for radiography
equipment in the workspace

RADIOGRAPHIC EXAMINATIONS
A doctor or individuals that possess the appropriate authority as permitted by their scope of practice may prescribe all x-ray examinations and “retakes” [Rule .0603(a)(1)(F)]. The UNC SCHOOL OF DENTISTRY clinic adheres to this rule by providing radiographic examinations only when ordered by licensed dentists in the state of North Carolina or individuals who are under their direct supervision.

OPERATING THE NOMAD PRO HANDHELD X-RAY SYSTEM FOR INTRAORAL IMAGING

While operating this device the user shall:

1. **Do not allow anyone in the room with the patient during an x-ray examination or closer than six feet which ever is applicable.** If other persons are needed to assist with the examination, they must wear lead aprons and must follow safe radiation procedures and keep out of the direct path of the beam.
2. Properly and optimally aim the device as recommended for each exposure during training. Also, always maintain visual and aural contact with the patient during the procedure.
3. Use image holders for all examinations to eliminate patients from holding image receptors with their hands. [.0603(a)(1)(H)]
5. follow the exposure guides (exposure time) and don't rely on memory for setting techniques. [Rule .0603 (a) (1) (C)] Technique guides should be maintained and updated as needed and their proper use should result in diagnostic images.

SHIELDING OF OPERATOR AND PATIENT

1. The operator will hold the Nomad Pro Handheld X-Ray System for Intraoral Radiographic Imaging as suggested in the training and maintain it at least 6 feet away from any one other than the patient.
2. Patients will be provided with a lead apron while undergoing a radiographic procedures. [Rule.0603(a)(1)(F)]
3. Never allow the patient to hold the Nomad Pro Handheld X-Ray System during the exposure.
4. When the Nomad Pro Handheld X-Ray System is used in an opened area, make a clearly audible announcement that the Nomad Pro Handheld X-Ray System is being used.
**PRINCIPLES OF ALARA**

All forms of radiation is potentially harmful: In accordance with [Rule .0603(a)(1)(I) & .1606 (b)] the use of the Nomad Pro Handheld X-Ray should be optimize to maximize the ALARA (As Low As Reasonable Achievable) principle. (See Appendix B – quick reference).

**Pregnant users of the** Nomad Pro Handheld X-Ray System are required to inform the RSO of their status and are required to read and sign information regarding the pregnancy policy and their rights (See Appendix C- quick reference).

There are no established contraindications for obtaining dental radiographs on pregnant patients if treatment necessitates radiographic images. However, The patient will be given the option to decline x-rays.

**RADIATION EXPOSURE LIMITS AND MONITORING**

**Personnel (Monitoring)**
The UNC SCHOOL OF DENTISTRY clinic operates with volunteers and anyone who uses the Nomad Pro will be required to wear A Victoreen 541L pocket dosimeter provided on site. At the end of the volunteer’s shift the pocket dosimeter will be read and a record of the measurement will be entered on a log. After each use, the pocket dosimeter will be re-zero before is provided to the next Nomad Pro user.

The pocket dosimeter should clipped to the collar or at the waist.

If you suspect there has been an excessive exposure or radiation incident, immediately notify the RSO

**Occupational Exposure**
Annual limits are as follows:
1. the total effective dose equivalent being equal to five rems (5000 millirems) (0.05Sv); or
2. the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv); and

The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:
1. an eye dose equivalent of 15 rems (0.15 Sv), and
2. a shallow-dose equivalent of 50 rems (0.50 Sv) to the skin of the whole body or to the skin of any extremity.

The annual limit for a declared pregnant volunteers or patient is .05 rem (500 millirems/ pregnancy)
**General Public Exposures**
Each licensee or registrant shall conduct operations so that:

1. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year.
2. The dose in any unrestricted area from external sources of radiation, does not exceed 0.002 rem (0.02 mSv) in any one hour.

**Note:** If annual exposure is expected to be above 10% of the dose limit the worker is required to be monitored. Dental personnel receive annual doses of less then 100 millirems.

**Exceeding Exposure Limits [15A NCAC 11 .1647]**
In accordance to the above rule, the UNC SCHOOL OF DENTISTRY Clinic will provide a report to the NC Department of Environment and Natural Resources, Radiation Protection Section when normal limits are exceeded.

**QUALITY ASSURANCE PROGRAM**

The UNC School of Dentistry will monitor the quality of the Nomad Pro Handheld X-Ray System by maintaining and checking its integrity as recommended by the manufacturer.

**Appendix A**
SAFETY PROCEDURE INSTRUCTION AND SAFETY OPERATION OF X-RAY EQUIPMENT.

In accordance with NCRFPAR, these procedures have been made available to each individual who operates the Nomad Pro Handheld X-Ray System for Intraoral Radiographic Imaging. I certify that each of the individuals listed below has demonstrated to me, on the date indicated, that he/she is competent in these operating and safety procedures and can operate the Nomad Pro Handheld X-Ray System for Intraoral Radiographic Imaging a safe manner.

________________________  ____________________________  __________________
Name of Nomad Pro user    Signature of Operator   Date

________________________  ____________________________  __________________
Name of Nomad Pro user    Signature of Operator   Date

________________________  ____________________________  __________________
Name of Nomad Pro user    Signature of Operator   Date

________________________  ____________________________  __________________
Name of Nomad Pro user    Signature of Operator   Date

Operator Statement:

I have read these procedures and agree to abide by them.

Appendix B
ALARA

**Rule .0104**

(10) “as low as reasonably achievable” making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

Since the mid-1950’s radiation safety standards have included provisions for incorporating the philosophy of As Low As Reasonably Achievable in safety programs.

(65) **DOSE LIMITS** “Limits” or “dose limits” means the permissible upper bounds of radiation dose. Dose limits represent an acceptable level of potential risk and do not represent a level that will necessarily be unsafe if they are exceeded.

**Rule .1604 (a) The licensee or registrant shall control the occupational dose to individual adults**

- Total effective dose equivalent (TEDE) being equal to five rems (5000 mrem) (0.05Sv), which is the NRC occupational dose limit.
- Total effective dose equivalent for general public, non-occupational dose limit is 0.1 rems (100 mrem) (1 mSv)
  - Total Organ dose equivalent (TODE) is 50 rems (50,000 mrem) (.5 Sv)
  - Eye dose equivalent 15 rems (15,000 mrem) (.15 Sv).
  - Shallow dose equivalent (SDE) 50 rems (50,000 mrem) (.5 Sv).

The facility should set action limits for the eventuality for exposure.

- Level I - Those persons with TEDE that are less than one tenth the acceptable dose limit for occupational and non- occupational- No action is necessary
- Level II - Those Exposures should be reported to Radiation Safety Committee by the RSO
- Level III - The RSO will investigate the cause of the high exposure, and any necessary preventive action. An incident report may be needed.

**Rule .1641 Records of Dose to Individual Members of the Public**

(a) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with dose limit for individual members of the public required by **Rule .1611**. These records may include such things as survey results, monitoring results, calculations and other documents pertaining to the determination of doses to individual members of the public.

(b) The licensee or registrant shall retain the records required by paragraph (a) of this rule until the agency terminates each pertinent license or registration requiring the record.
Appendix C

Special Considerations for the Pregnant Radiation Employee

Effects of Exposure to Radiation and Other Environmental Hazards

This document attempts to explain the risks associated with radiation and pregnancy and compares these risks with other risks to the unborn child. This will assist the pregnant, occupationally exposed employee in assessing the potential risk to the unborn child during the course of employment. Also discussed are methods of minimizing the radiation dose and the risk to the unborn child and maintaining the radiation doses as low as reasonably achievable. Everyone is exposed daily to various kinds of radiation: heat, light, ultraviolet, microwave, ionizing, and so on. All human activities involve exposure to radiation. People are exposed to different amounts of background ionizing radiation depending on where they live, what they eat and drink, and how they live. Background radiation comes from many sources: radon, soil, rocks, cosmic rays, water, air, consumer products, etc. The average person is exposed to approximately 360 mrem per year from these background sources of ionizing radiation.

To understand the potential effects of different levels of radiation on an embryo/fetus, it is helpful to compare them to the naturally occurring effects and the environmentally produced risks such as smoking and drinking. This will allow someone to contrast these risks with those produced by exposure to ionizing radiation.

The natural risks for birth defects are as follows:
3-5% of all births have some type of abnormality detectable at birth and 3-5% of all births have some type of condition or disease that develops later in life (not detectable at birth). The risk of a known pregnancy ending in a miscarriage or stillbirth is 20-30%.
The following table compares the radiation risks (childhood cancer, abnormalities) and nonradiation risks (stillbirth or spontaneous abortion due to high-risk occupations such as the lead industry, fetal alcohol syndrome and perinatal death due to alcohol or smoking) with their natural occurrence as birth defects.

References:
Nuclear Regulatory Commission and the North Carolina Radiation Protection Section

Regulations and guidance are based on the conservative assumption that any amount of radiation, no matter how small, can have a harmful effect on an adult, child, or unborn child. Because it is known that the unborn child is more sensitive to radiation than adults, particularly during certain stages of development, a special dose limit for protection of the unborn child has been established. Such a limit could result in job discrimination for women of childbearing age, and perhaps an invasion of privacy (if pregnancy tests were required). Therefore, the regulatory agencies have taken the position that special protection of the unborn child should be voluntary and should be based on decisions made by workers and by employers who are well informed about the risks involved. It is important that the employee understand the risk to the unborn child from radiation received as a result of the occupational exposure of the mother.

Radiation Dose Limits

Because of the sensitivity of the unborn child, the North Carolina Regulations For Protection Against Radiation and the Code of Federal Regulations Part 20 have recommended that the dose equivalent to the unborn child from occupational exposure of the expectant mother be limited to 500 mrem for the entire pregnancy. This radiation exposure limit can only be enforced if the mother declares the pregnancy. A declared pregnancy is one in which a woman voluntarily informs her employer, in writing, of her pregnancy and gives the estimated date of conception. An employee can declare her pregnancy by filling out a Pregnancy Certification Form available from Radiation Safety.

Advice for Employee and Employer

Although the risks to the unborn child are small under normal working conditions, it is a regulatory requirement to limit the radiation dose from occupational exposure to not more than 500 mrem for the total pregnancy and to not more than 50 mrem in any month. Employee and employer should work together to decide the best method for accomplishing this goal. Some methods that might be used include: reducing the time spent in radiation areas, wearing some shielding over the abdominal area, and keeping an extra distance from radiation sources when possible. The Radiation Safety Officer will be able to estimate the probable dose to the unborn child during the normal nine-month pregnancy period based on the exposure history. If the predicted dose approaches the limit, the employee and employer should work out schedules or procedures to confine the dose to less than the 500 mrem required limit.

Internal Hazards

Workers should be aware that radiation exposure to the fetus could be from internal sources as well as from external sources. In workplaces such as nuclear medicine clinics and research laboratories where unsealed radioactive materials are routinely used, there is a greater risk of radioactive material entering the body. Pertinent standard radiation precautions include the following:
1. Never smoke, eat, drink, or apply cosmetics where radioactive materials are used.
2. Never pipette by mouth.
3. Use disposable gloves while handling radioactive materials.
4. Wash hands and monitor for radioactive contamination frequently.
5. Wear lab coats or other protective clothing around loose radioactive material.
6. Use certified ventilation hoods when handling volatile or potentially volatile radionuclides.

**NORTH CAROLINA RADIATION PROTECTION SECTION**

**Quick Reference Guide**

**Pregnancy-Employee/Patient**

**Rule .1610**

(a) The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). Record keeping requirements for doses to an embryo/fetus are provided in Rule .1640.

(b) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this rule.

© The dose to an embryo/fetus shall be taken as the sum of:

(1) the deep-dose equivalent to the declared pregnant women; and

(2) the dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this rule, if the additional dose to the embryo/fetus does not exceed 0.05 rem (.5 mSv) during the remainder of the pregnancy. In recognition of the possibility of increased radiation sensitivity, and because dose to the embryo/fetus is involuntary on the part of the embryo/fetus, this more restrictive dose limit has been established for the embryo/fetus of a declared pregnant radiation worker.

**Rule .0104**

As a rule the following definitions shall apply.

(28) “Declared pregnant woman” means a woman has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(42) “Embryo/Fetal” means the developing human organism from conception until time of birth.

A number of studies have suggested that the embryo/fetus may be more sensitive to ionizing radiation than adults, especially during the first trimester of gestation. The National Council on Radiation Protection and Measurement (NCRP) has recommended that special precautions be taken to limit exposure when an occupationally exposed woman could be pregnant. Genetic effects are those that affect the offspring of exposed persons, usually in the range of 20-200 rem. At normal exposure levels, genetic effects of radiation are negligible.
It is the responsibility of the Radiology employee to inform (declare) the supervisor that they may be pregnant, this declaration should be in writing, with estimated due date. Until there is a declaration of pregnancy, the occupational dose limits shall remain those guidelines set for adult employees.

**Declaration of Pregnancy should include:**
Your name
Estimated date of conception/or due date
The date you signed the Declaration of Pregnancy
To declare pregnancy, no documented medical proof is necessary. **MUST BE IN WRITING.** This legally protects the employee and the employer

Once declaration of Pregnancy is signed:
Employee should be counseled by her supervisor and/or the RSO, to include:
1. Review of exposure history
2. Educational review on exposure levels for unborn children (maximum permissible dose, 0.5 rem) and fetal risk associated with exposure to radiation.
3. Discussion of employees work schedule, supervisor, RSO or employee may ask for reassignment to minimize exposure.
4. Supply Declared pregnant worker with a monitor for fetal dose.

**Availability of additional information**

**Rule .1640 Record Keeping**

(f) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from dose records.

The general principles for maintaining exposure to radiation as low as reasonable achievable are time, distance and shielding.
Decrease your time near radiation source, increase your distance from the radiation source, and increase the shielding between you and the radiation source.

**For Patients who may be pregnant**

All patients in their reproductive years between 12 and 45 should be questioned as to the possibility of pregnancy. This should be done as sensitively and unobtrusively as possible, in keeping a woman’s privacy and dignity in tact. If there is the possibility that pregnancy is likely, the Radiologist should be notified and a pregnancy test should be recommended.

If the patient is pregnant:

Attending/referring physician should be notified
Physician should decide if x-ray is necessary at this time
If needed, patient must be thoroughly informed of risks associated with radiation and the embryo/fetus- the decision for x-ray-s exam must be left up to the patient.
If the patient decides to proceed with the x-ray examination, the patient should be shielded, shielding shall be documented and a signed waiver should be obtained. If the exam is in the abdominal region, a modified x-ray exam may be necessary, consult with the physician and/or RSO
**Rule .1611** The Lower limit for declared pregnant radiation worker is 0.5 rem, but for the general population the limit from licensed or registered operations is not to exceed 0.1 rem (1 mSv) in a year. The risk to embryo/fetus from 0.5 rem or even 5 rem of radiation exposure is relatively small compared with some other avoidable risk, such as alcohol consumption and cigarette smoking.
Appendix D

FORM LETTER FOR DECLARING PREGNANCY
(copy and file in employee’s file)

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter, you may use a form letter the licensee has provided to you, or you may write your own letter.

DECLARATION OF PREGNANCY

To: _________________________

In accordance with the NRC’s regulations at 10 CFR 20.1208, "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in________________ (only the month and year need be provided).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 0.5 rem (5 millisievert) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_________________________________________
(Your Signature)

_________________________________________
(Your Name Printed)

_________________________________________
(Date)