Minnesota Department of Health Radiation Control, X-ray Unit

Protecting, maintaining and improving the health of all Minnesotans by promoting radiation safety through guidance and collaboration with the radiation community

X-RAY REGULATORY GUIDE



SELF-REFERRAL COMPUTED TOMOGRAPHY SCREENING APPLICATION



Radiation Control, X-ray Unit 625 North Robert Street PO Box 64497 St. Paul, Minnesota 55164-0497 651-201-4545 <u>www.health.state.mn.us/xray</u> health.xray@state.mn.us January 23, 2015

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INTRODUCTION TO THE REGULATORY GUIDE FOR SELF-REFERRAL COMPUTED TOMOGRAPHY SCREENING REGISTRANTS

Minnesota Department of Health Mission, X-ray Program Mission

The mission of the Minnesota Department of Health (MDH) Radiation Control X-ray Unit is to protect and promote radiation safety through guidance and collaboration with the radiation community. Our vision is to reduce unnecessary radiation exposure from the use of ionizing radiation producing equipment.

Introduction

The Minnesota Department of Health (MDH) regulates the testing of individuals with x-ray equipment to detect or evaluate health conditions when the tests are not specifically and individually ordered by a licensed practitioner of the healing arts authorized to prescribe the tests for the purpose of diagnosis or treatment. This type of use is called healing arts screening or Computed Tomography (CT) self-referral screening. A specific application and approval from the Commissioner is required before this examination can be performed. The regulations governing CT self-referral screening are contained in the Ionizing Radiation Minnesota Rules, Chapter 4732.

The applicant must meet the requirements in Minnesota Rules, Chapter 4732 and must be registered with the Commissioner before an application for CT self-referral screening is initiated. Submit the required information in <u>Minnesota Rules, Chapter 4732.0565</u> along with MDH application for CT self-referral screening. This form can be found on the MDH website at <u>http://www.health.state.mn.us/divs/eh/radiation/xray/medical.html</u> or in Appendix A of this guidance document. You should carefully study this guide and all the regulations identified in Minnesota Rules, Chapter 4732.0565 before completing the application form.

This guide is designed to describe the type and extent of information needed by MDH in order to evaluate an application for an approval for CT self-referral screening and to describe the internal process of your radiation protection program within your organization.

After an approval is issued, the registrant must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with MDH;
- Terms and conditions of the application; and
- MDH rules.

MDH requires the information in the application to be complete and accurate in all aspects. Information is considered relevant if it has the ability to change or affect the Commissioner's decision to issue an approval of your application. MDH may request additional information when necessary in order to provide reasonable assurance the applicant has established an adequate radiation protection program.

The information in this guide is not a substitute for radiation safety training or for developing and implementing an effective radiation safety program for CT self-referral screening. You

should carefully study this guide and MDH Minnesota Rules, Chapter 4732 on radiation to ensure you have an adequate radiation protection program.

http://www.health.state.mn.us/divs/eh/radiation/xray/rules/index.html

This guidance, instruction sheets, and additional information, is available on the X-ray Unit website as they are developed.

http://www.health.state.mn.us/xray

Implementation

The information in this regulatory guide is *guidance*, not requirement. MDH reviews each application to ensure that individuals applying for CT self-referral screening are capable of complying with MDH rules. This guide provides one set of methods approved by MDH for meeting the regulations and represents the minimum acceptable standards. If you have questions, please contact the Radiation Control, X-ray Unit at (651)201-4545 or email at <u>health.xray@state.mn.us</u>.

Inspections

MDH conducts inspections of new radiological programs with subsequent routine inspections that are performed on a 3 year cycle. The routine CT inspections are unannounced and will review your CT self-referral screening program for compliance at the time of inspection. In the event MDH receives a call of concern regarding your x-ray operations, investigational inspections may be performed.

Revisions to the Self-Referral Computed Tomography Screening Application Regulatory Guide

MDH X-ray Unit is always striving to better the information that we provide to our registrants. This may include additions to the information presented in this guide. There may be occasion for revisions to this guide. These revisions are not changes to Minnesota Rules, Chapter 4732 and are intended to clarify or supplement what is already within the guide.

Any revisions to this guide will be documented in the Summary of Revisions at the end of this guide.

AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY (<u>4732.0200</u>)



Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable (ALARA). As an applicant, you should consider the ALARA philosophy in the development of work plans involving your procedure and protocol for CT self-referral screening examinations.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

The registrant must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to the public that are as low as is reasonably achievable and do not exceed the dose limits.

The Radiation Safety Officer (RSO) and management are required to implement and audit the radiological protection program to ensure the continued safe use of procedures and quality assurance program and its implementation annually. The RSO is also responsible for the day-to-day operations of the radiation safety program. A model ALARA management program is contained in Appendix B of this guide.



FILING AN APPLICATION (4732.0500)

To apply for an approval of CT self-referral screening, complete the "Application for CT screening." Complete Items 1 through 4 on the form itself. For Items 5 through 18, submit the information on supplementary pages. Identify each sheet or document with the item number on the application. All typed pages, screening protocols, and, if possible, detailed description of the x-ray equipment and facilities should be on 8 1/2 X 11 inch paper to facilitate handling and review. Complete and submit documents electronically to <u>health.xray@state.mn.us</u>. Items in the application must have sufficient detail for MDH to determine that your equipment, facilities, training and experience, and radiation safety program is adequate to protect the health and safety of the public as well as your employees.

Please note that CT self-referral screening applications are available in the MDH office for review by the general public. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training, qualifications, and experience of individuals must be submitted to demonstrate their ability to manage radiation safety programs or specific qualifications to work safely with CT equipment. Dates of birth, social security numbers, and radiation dose information should not be submitted and will not be specifically requested by MDH.

If unable to submit application electronically to <u>health.xray@state.mn.us</u> submit one copy of your application to:

Minnesota Department of Health Radiation Control, X-ray Unit Application for CT Screening PO Box 64975 St. Paul, MN 55164-0975

Retain one copy for yourself, as the approval will be issued based on the statements and representations in your application, its supplements, and the requirements in the regulations. The statements and representations you make will bind you as if they were regulations. If you have changes to your CT self-screening program within your approval period, the applicant is responsible for informing the Commissioner of any changes in the screening program described in the application. The applicant must obtain Commissioner approval of the changes before the implementation.

ITEM 1: APPLICATION ACTION TYPE

Check box A for a new applicant request.

Check box B for a revision to an existing approval and provide your facility registration number. See "Revisions and Renewals to Screening Program," section of this document.

Check box C for a renewal of an existing approval of a CT self-referral screening program and provide your facility registration number.

Please check the boxes of each CT self-referral screening program(s) for which you are applying. A separate application is not required for each screening program. If applying for multiple screening programs, submit documentation for each screening area when appropriate during this application.

Each registrant will receive one approval letter from MDH. Separate approvals will not be normally issued to different departments within one organization. A registrant will have one expiration date for all areas applying. If a registrant determines to add an additional area of screening during their approval period, it will be considered a revision to their program. The existing expiration date on their approval letter will remain the same.

ITEM 2: NAME AND MAILING ADDRESS OF APPLICANT

List the legal name of the applicant's corporation or other legal entity with direct control over use of the CT unit; a division or department within a legal entity may not be an adequate name. The specific facility name should correlate directly with the registration MDH has on file for your organization. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the CT unit is not connected with employment in a corporation or other legal entity. Provide the mailing address for correspondence.

ITEM 3: ADDRESS(S) WHERE SELF-REFERRAL SCREENING WILL BE PERFORMED

Applicants must provide a specific address for each location performing CT self-referral screening examinations. If the screening site name differs from the legal entity name or registrant name MDH has on file for your registration number, please specify the site name. In addition, specify the street address, city, and state where your CT self-referral screening examinations are performed if different than the registration number MDH has on file. A Post Office Box address is insufficient because MDH needs a specific address for inspection purposes.

CT Self-Referral Screening Through Mobile Services

In general, there are two types of mobile medical services. One type is transportation and use of a CT unit within a transport vehicle (e.g., in-van use). A second type is transportation of a CT unit to a client's facility for use within a client's facility by the mobile medical service's employees (i.e., transport and use).

The base location for the mobile medical service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, commercial facility, or mobile van. Applicants should specify in what type of facility the proposed base facility is located.

If the screening is performed through a mobile service at different locations than the registrant address, provide the information in the box below for all locations performing CT self-referral screening. Use a separate sheet to itemize the different locations with all the adequate information listed: name of mobile site, address, site contact name, site contact phone number, and site contact email.

Mobile Service Site Location(s)				
Mobile Site Name				
Site Address				
City, State, Zip				
Site Contact Name				
Site Contact Phone				
Site Contact Email				

If the mobile service is based outside Minnesota, the imaging service must submit notification to MDH three days prior to entering the state with the reciprocity notification form located on our website at <u>http://www.health.state.mn.us/divs/eh/radiation/xray/reciprocity.html.</u> Indicate at the top of the form CT self-referral notification.

ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Identify the individual and title for which MDH may address questions about the application and include his or her telephone number and email address. This is typically the proposed radiation safety officer (RSO) or knowledgeable management official.

Notify MDH if the contact person or telephone number changes within the approval period. This does not require an application revision to be submitted.

ITEM 5: PURPOSE(S) FOR THE SCREENING PROGRAM

When a patient chooses to be screened without consulting a licensed practitioner of the healing arts, it is particularly important to protect individuals and the general public from unnecessary radiation exposure resulting from CT self-referral screening programs. Indicate the determinants used for selection of patients and age of patients to be screened. Submit nationally recognized standards or provide a copy of registrant specific guidelines and criteria your organization is following for each area applying for CT self-referral screening.

The applicant should indicate the purpose of the proposed CT self-referral screening program. The purpose must include the diseases or conditions for which the x-ray examinations are to be used in diagnosis. All diseases or conditions must be submitted for review for a CT self-referral screening application to be approved.

ITEM 6: DETAILED DESCRIPTION OF THE X-RAY EXAMINATION, FACILITIES, AND EQUIPMENT

Describe the equipment manufacturer and model of each CT unit for performing CT self-referral screening. Include the specific serial number for each scanner, enabling MDH to adequately identify the registration of the particular unit(s). If more than one scanner is utilized for CT self-referral screening, the applicant must submit documentation for all scanners performing these examinations. During the MDH inspection, the inspector will ensure your CT self-referral screening is only being performed on approved scanners submitted during the application process. Describe your facilities process to ensure your non-approved scanners are not being utilized for your CT self-referral screening program.

The applicant must submit a detailed description of the CT protocol proposed in the screening program. The protocol for each of your CT self-referral screening areas you are applying for must have a site specific protocol that describes the parameters of the scan, detailed capabilities of the scanner, and orientation of the patient. For example, your outline should display and contain but are not limited to; AEC capabilities, scan acquisition, kVp, rotation time, mA, beam collimation, image thickness, and FOV factors. Explanations should identify whether you are performing both prone and supine imaging, have gating capabilities included during examination, protocols for an average patient, if more than one protocol is used for larger patients, and possess software that reduce dose like ASIR (GE) or IRIS (Siemens). The description of protocols being used during the examination necessitates a clear image is obtained for accurate diagnosis and to ensure the exposure is minimized.

ITEM 7: DETAILED DESCRIPTION OF POPULATION EXAMINED

All applicants need to describe the population to be examined for each CT self-referral screening program area. For example, age, sex, physical condition, and other appropriate information. Minors will not be approved for CT self-referral screening.

Indicate patient gender for each CT self-referral screening imaging and describe age distribution of population to be screened and how the age's determination was derived. If female patient age is within child bearing years, please submit procedures to ensure the female population are not pregnant prior to the examination.

The patient's physical condition or disease process to be ruled out should be listed in it's entirely. This information must correlate with the purpose for your screening program in Item 5.

ITEM 8: EVALUATION OF ALTERNATIVE METHODS

Evaluate any known alternate methods involving/not involving ionizing radiation that could achieve the same goals for the cardiac, lung, or colon CT self-referral screening examination. Indicate other exams that may be performed in conjunction with, or as an adjunct to the screening procedure. Explain why these methods are not being used instead of the CT self-referral x-ray examinations. Specify the necessity of using ionizing radiation in place of other screening procedures. This explanation should be provided for each area you are including in the application.

ITEM 9: EQUIPMENT PERFORMANCE EVALUATION

Evaluation of CT units performing self-referral screening must have an annual equipment performance evaluation (EPE) performed by a diagnostic radiological physicist. The evaluation must show the system satisfies all requirements outlined in Chapter 4732 Ionizing Radiation regulations. Submit a copy of the current diagnostic radiological physicist EPE for each CT unit performing self-referral screening examinations. The EPE must not expire within the review and approval timeframe. A current EPE will be requested prior to approval.

"Diagnostic radiological physicist" is defined as an individual who is qualified to practice independently in the appropriate subfields for medical diagnostic physics and is:

- A. Certified in radiological physics or diagnostic radiological physics by the American Board of Radiology;
- B. Certified in diagnostic physics by the American Board of Medical Physics;
- C. Certified in diagnostic physics by the Canadian College of Medical Physics; or
- D. A holder of a master's degree in medical physics.

The registrant applying must submit the name and Minnesota Service Provider number (MNSP#) of the diagnostic radiological physicist performing their organization's EPE's. Submit a list of additional service providers working with your equipment as well as their Minnesota Service

Provider number. MDH will use this information to ensure all individuals are registered service providers in Minnesota.

"Service Provider" is defined as a person engaged in the business of assembling, installing, repairing, or replacing one or more components into diagnostic or industrial radiation producing equipment system or subsystem or conducting equipment performance evaluations on diagnostic or industrial equipment. Service providers must be registered with the commissioner under <u>Minnesota Rules, Chapter 4732.0275.</u>

Application Specialists currently under Chapter 4732 are not required to be registered as a Minnesota Service Provider. Exemptions to <u>Minnesota Rules</u>, <u>Chapter 4732.0275</u> are individuals employed by a registrant to perform "in house" calibrations, EPE's, or repairs of diagnostic or industrial radiation producing equipment. These individuals are exempt from registering as service providers. An "in house" employee may not perform these tasks elsewhere unless registered as a service provider.

ITEM 10: MEASUREMENT OF PATIENT EXPOSURES

For each screening area, submit the CTDIvol dose value from each CT unit performing selfreferral screening examinations. The CTDIvol dose value must be from the factors submitted in Item 6, which are based on the factors programmed in your scanner. Submit the "Site" estimated CTDIvol using the measured "Site/Vendor" CTDIvol correction factor obtained for an abdomen scan using a 32cm diameter CT Dosimetry phantom.

ITEM 11: DESCRIPTION OF QUALITY ASSURANCE PROGRAM

"Quality Assurance Program" means an all-encompassing program including quality control that extends to administrative, education, and preventive maintenance methods. It includes a continuing evaluation of the adequacy and effectiveness of the overall imaging program with a view to initiate corrective measures when necessary. The nature and extent of this program will vary with the size and type of the facility and the type of activities conducted.

The applicant must submit the implemented site-specific diagnostic x-ray quality assurance program outlined in 4732.0520 which includes, but is not limited to:

- 1. ALARA program
 - Model ALARA program is listed in Appendix B of this guidance document
- 2. Operating & Emergency procedures for your CT scanner
- 3. Radiation program audits
 - Suggested annual audit checklist is listed in Appendix C of this guidance document
- 4. A copy of the delegation of authority for your Radiation Safety Officer (RSO)
 - RSO responsibilities and example of a delegation of authority letter is listed in Appendix D of this guidance document
- 5. Description of training for the individuals qualified to perform CT self-referral screening examinations

- Training description is listed Appendix E of this guidance document
- 6. Procedure of your retake/reject analysis program
 - Guide for CT retake/reject analysis is listed Appendix F of this guidance document
- 7. Explain the frequency of each Quality Assurance or Quality Control performed on the CT scanner
 - Diagnostic Radiological Physicist Equipment Performance Evaluation
 - Preventative Maintenance by manufacturer specific engineer
 - Technologist testing performed with manufacturer specific phantom prior to scanning patients
 - Quality Control testing performed daily on dry view processor

As Low As Reasonably Achievable (ALARA)

"As low as is reasonably achievable" or "ALARA" is defined as making every reasonable effort to maintain exposure to radiation as far below the dose limits as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvement in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

Operating and Emergency Procedures

Develop, implement, and maintain specific operating and emergency procedures containing the following elements in accordance with applicant's radiation protection program required by <u>Minnesota Rules, Chapter 4732.0520</u> and <u>Chapter 4732.0860</u> during an event of a CT equipment malfunction. These procedures may include but are not limited to:

- Terminate procedure with Emergency "Off", follow manufacturer's Emergency Procedures
- Remove Patient from couch
- Contact the Radiation Safety Officer
- Contact service provider (if necessary)

Holding of Patient and Lead Apron usage

- Individuals must not hold patients or image receptors unless the individual has been instructed in personal radiation safety and is protected by a 0.5 millimeter lead equivalent apron
- Only individuals necessary for the exam may be allowed in the room during a CT exposure
- Lead apron use is required for any individual that must remain in the CT room during an exposure

AND

The registrant must consider the following:

- Make operating procedures, including emergency procedures, available to all users
- Maintain a current copy of the procedures at each location of operation
- When developing the procedures described above, the registrant is reminded that, to the extent practical, the operator must use procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA

Training Requirements

An individual operating radiation producing equipment must be instructed initially in sitespecific and system specific safe operating procedures, emergency procedures, quality control procedures, and the use of proper protective shielding. Additional training must be conducted at the time of any change to the quality assurance program or change in radiation output. Applicants must submit how technologists are trained on your approved self-referral screening program.

Annual Audit of the Radiation Safety Program

All registrants must annually review the content and implementation of the radiation protection program. The review should ensure the following:

- Compliance with MDH Chapter 4732 Ionizing Radiation regulations; and
- Occupational doses and doses to members of the public are ALARA.

The applicant should develop and implement procedures for the required review or audit of the radiation protection program's content and implementation.

MDH encourages management to conduct performance based reviews by observing work in progress, interviewing staff about the radiation protection program, and spot checking required records. As part of their review programs, registrants should consider performing unannounced audits of qualified technologists to determine if, for example, *Operating and Emergency Procedures* are available and are being followed.

It is essential that once identified, violations and radiation safety concerns are corrected comprehensively and in a timely manner. The following three step corrective action process has proven effective:

- Conduct a complete and thorough review of the circumstances that led to the violation
- Identify the root cause of the violation
- Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violation

MDH's goal is to encourage prompt identification and comprehensive correction of violations and deficiencies.

Radiation Safety Officer

The oversight of the radiation safety officer is essential in providing the registrant with information needed to maintain the safe operation of the radiation producing equipment in the facility. The radiation safety officer is vital and is necessary to protect the public health from radiation hazards and implement precautions involving the operation of radiation producing equipment.

The radiation safety officer must agree in writing to be responsible for implementing the radiation protection program. The individual designated as a radiation safety officer must be

either a licensed practitioner of the healing arts; or an individual who has completed training in the following items:

- Fundamentals of radiation safety
- Familiarization with facility's radiation producing equipment
- Film processing, if applicable
- Digital imaging, if applicable
- Quality assurance program
- Audits of the quality assurance program
- Emergency procedures for radiation producing equipment failures
- Proper use of personal dosimetry, if applicable
- Requirements of pertinent state rules
- Registrant's written operating and emergency procedures

Repeat/Reject Analysis Program

"Retake" or "reject" is defined as any diagnostic radiographic imaging that had to be retaken, reexposing the patient to radiation because of some error, failure, or degradation in the radiographic imaging process.

"Retake or reject analysis program" is defined as an ongoing analysis of retakes or rejects that provides information about existing imaging problems in a radiology department.

Equipment Performance Evaluation

Equipment performance testing is necessary because of the complexity of these devices, to provide diagnostic images of good quality and keep exposure of the patient as low as reasonably achievable. These performance measurements must be performed annually for CT to ensure that the equipment is functioning at the manufacturer's specifications and the radiation output has not changed. This information provides assurance that the operator, patient and members of the public are not receiving unnecessary radiation exposure. For any parameter found to be out of tolerance, corrections must be made. If a parameter has been exceeded, the unit cannot be used on patients until the condition has been corrected and verified with further tests.

Annually is defined as an activity that is done or is performed at intervals not to exceed 12 months.

ITEM 12: TECHNIQUE CHART FOR X-RAY EXAMINATION

The technique chart in item 12 is essential to ensure that patient radiation exposure is as low as reasonable achievable and a diagnostic image is obtained for accurate diagnosis. This technique chart must be located within the vicinity of the control panel. For CT systems, a current technique chart for each routine examination and the CT conditions of operation must be provided. Diagnostic radiation producing equipment manufactured with anatomical programming within their console is exempt from having a separate technique chart, however, you are still required to submit a technique chart for obtaining a self-referred screening approval.

The technique chart must correlate with the detailed description of the examination that was submitted in item 6. Listed in Appendix G of this guidance document is an example of a technique chart for a CT unit.

ITEM 13: QUALIFICATIONS OF TECHNOLOGISTS

Only individuals who have met the operator of x-ray equipment qualification requirements may perform CT imaging. The lists below are examples of qualified individuals, individuals listed are not all inclusive and MDH must be contacted for individuals not specifically listed.

- Individuals who have taken and passed the American Registry of Radiologic Technologists examination (ARRT)
- Individuals who have taken and passed the Minnesota X-ray Operators examination prior to January 1, 2008
- Individuals who have passed the Limited Scope Operator examination is not qualified to perform CT or Fluoroscopy examinations

The applicant must list all of the individuals who will be performing CT self-referral screening examinations and submit a copy of their current qualifications. The qualification can be a copy of their ARRT card or an electronic copy from the ARRT website. Indicate and submit any type of specialized CT training the technologist has received.

Because some commercial models allow each imaging modality to be used separately, MDH has made a determination regarding the operator requirements for operating this dual imaging device. If you are a registrant utilizing PET/CT technology combining a nuclear medicine imaging device and a radiologic imaging device into one unit for CT self-referral screening adhering to the qualifications listed below is required.

- 1. When a unit is operated as a nuclear medicine imaging device, the operator must be a nuclear medicine technologist
- 2. When the unit is operated as a radiologic imaging device, the operator must have passed an x-ray operator examination or equivalent
 - The daily quality control must only be performed by an individual registered with ARRT for Radiologist Technologists or has passed the Minnesota x-ray Operators examination
- 3. When the unit is operated as a dual imaging device, it is considered a nuclear medicine technology procedure rather than a radiologic technology procedure for the following reasons:
 - Radiopharmaceuticals are injected

- The device may use radioactive material as point sources in transmission scanning and attenuation correction
- The nuclear medicine procedure involves a greater potential for radiation safety problems (including dose to the patient, employees, and the public) as well as potential contamination of areas within the facility

ITEM 14: QUALIFICATIONS OF INDIVIDUAL SUPERVISING

The qualifications of the individual supervising the operators for CT self-referral screening must be submitted with this application. The supervisor of the program oversees the day-to-day function and process of the program and ensures the completeness of the application.

Documentation submitted must include:

- Qualifications of the individual supervising the operators
- Detailed description of the supervising individual's extent of oversight for managing the CT self-referral screening program
- Provisions for compliance with the approved screening application and MDH 4732 rules
- Ensuring corrective actions are taken when necessary

ITEM 15: QUALIFICATIONS OF INTERPRETING PHYSICIANS

Since an individual chooses to be screened without consulting a license practitioner, the images must be interpreted by a licensed practitioner of the healing arts. It is imperative to protect individuals from unnecessary radiation exposure resulting from CT self-referral screening examinations and by confirming oversight by a licensed practitioner of the healing arts ensures protection to these patients.

Submit a list all of the individuals who will be interpreting the images and the specific business address where they are to be interpreted. Submit a copy of all interpreting individual(s) qualifications and include any CT interpretation training. The qualification can be a copy of their professional license or an electronic copy from the medical board website.

ITEM 16: PROCEDURE FOR INFORMING INDIVIDUALS AND PRIVATE PRACTITIONER

The procedures for interpreting x-ray findings to the individual screened, sending the results to the individual, and recommended necessary follow-up treatment, must be specified.

Define your site specific procedures for notifying the patient and informing their private practitioners of the healing arts of the results or further recommendations. In the event where patients negate having a private practitioner or fail to list their private practitioner, provide a description of your procedures if further medical needs are indicated.

ITEM 17: RETENTION OF IMAGES ACQUIRED

Maintaining results given to the patient and the retention of the images and records relating to the CT self-referral screening procedure are a necessity. Screening procedures are unlike other x-ray procedures in that they are not ordered at the direction of a licensed practitioner of the healing arts.

Describe the retention or disposition of the radiographs and other records pertaining to your CT self-referral screening examinations. In your description explain the location and address of where the images and records will be stored, how long the images and records will be maintained and what will happen to your information if your facility chooses to terminate operation.

ITEM 18: FREQUENCY FOR SCREENING PATIENTS

Provide a site specific CT self-referral screening explanation justifying your established frequency for performing these examinations. If your facility follows a nationally recognized standards for the frequency at which patients are allowed to be examined, provide MDH with this documentation.

REVISIONS TO AN APPROVED APPLICATION

After you are issued an approval to your application, you must conduct your program in accordance with:

- 1. The statements, representations, and procedures contained in your application
- 2. The terms and conditions of the protocol and examination
- 3. The MDH rules

It is your obligation to keep your application current. You should anticipate the need for a revision to your program as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a revision and include the appropriate modifications prior to implementation.

The registrant may not place into effect any revisions until receiving written verification from MDH that the revision has been approved. The submittal of changes to the program is essential to ensure the changes do not result in unnecessary radiation exposure.

An application for a revision may be prepared on the *Application for CT Screening*. The application must identify the registration number and clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

Revision Example

If you wish to change the protocol used for your cardiac screening program, your application must specify the new detailed description of the protocol used in your scanner for the x-ray examination and dose specific measurements for your proposed screening area.

RENEWAL OF SCREENING PROGRAM

An application for the renewal of your screening program must be submitted in writing 30 days before the expiration date. Renewal requests must contain all the required information on the MDH Application for CT Screening. This will ensure that your previous approval will not expire before the final action on the application has been taken by MDH. The application for the renewal should not reference material that was previously submitted and must contain all items on application.

If you do not wish to renew your application for CT self-referral screening an expiration letter will be sent indicating your termination date of your CT self-referral program. Registrants performing CT self-referral screening after the specified expiration date may be subject to administrative penalties up to \$10,000. The renewal is necessary to avoid violating MDH Minnesota Rules, Chapter 4732, which do not allow you to perform CT self-referral screening without appropriate approval from MDH.

ANNUAL SCREENING QUESTIONNAIRE

Registrants approved by MDH to perform CT self-referred screening will receive, by email, an annual questionnaire each January to collect data regarding CT self-referred screenings performed the previous year. As part of the screening approval, each registrant is required to complete the questionnaire regarding all CT self-referred screenings performed the previous year. If the registrant chooses not to renew their application, completion of the questionnaire is still required. The survey will be emailed to the individual identified as the registrant contact on the screening application.

Information collected from this questionnaire is used to generate an annual CT self-referred screening report regarding Minnesota data. The report is intended to allow registrants and other entities to evaluate the CT self-referral screening program and exposure measurements. Registrants may use this data to review current screening practices relative to patient exposures and ALARA principles. All data collected will remain anonymous and no registrant will be specifically identified.

The annual report is posted online at: <u>http://www.health.state.mn.us/divs/eh/radiation/xray/screening.html</u>

The following data will be requested on the questionnaire:

- 1. Number of CT self-referred patients screened for each type of examination
 - Calculate the exact number of CT self-referral screening examinations performed by your facility for the entire calendar year
 - Indicate number for each area approved, i.e. cardiac, lung, colon
- 2. Number of positive results for each type of screening examination
 - The number of examinations that were interpreted with a positive finding
- 3. Type of scanner used in performing these examinations by detector configuration (slice)
 - Indicate the detector configuration (not the manufacturer or model of the scanner)

Note: If the CT scanner was upgraded within the year, both detector configurations must be given

- 4. Average total dose length product given to the patient in mGy-cm for each detector configuration (slice)
 - Actual CTDIvol in mGy calculated from factors programmed in CT scanner and should be viewable on patient identification page
 - Calculate the average total dose length product to the patient for the entire examination
 - The average measurements requested is the Dose-Length Product (DLP). This should not be an estimation of the patient effective dose (ED).

Note: If the CT scanner was replaced within the calendar year, average doses must be submitted for both scanners

APPENDIX A APPLICATION FOR COMPUTED TOMOGRAPHY SELF-REFERRAL SCREENING

	APPLICATION FOR CT SCREENING X-RAY UNIT PO BOX 64975 ST. PAUL, MN 55164-0975 651-201-4545					
INS NEC CAN THI HE/	INSTRUCTIONS: COMPLETE ALL ITEMS IF THIS IS AN INITIAL APPLICATION OR RENEWAL. USE SUPPLEMENTAL SHEETS WHEN NECESSARY IN FILLING THIS APPLICATION. MINNESOTA DEPARTMENT OF HEALTH COMPUTED TOMOGRAPHY (CT) SCREENING GUIDE CAN BE FOUND ON THE INTERNET AT <u>www.health.state.mn.us/xray</u> . TO ENSURE A COMPLETE AND ACCURATE APPLICATION, PLEASE USE THIS GUIDE AS A REFERENCE WHILE COMPLETING THIS APPLICATION. A LINK TO THE MINNESOTA IONIZING RADIATION RULE, 4732.0565 HEALING ARTS SCREENING CAN BE FOUND AT THE ABOVE WEB SITE.					
1.	 THIS IS AN APPLICATION FOR (Check appropriate item) A. NEW CT SCREENING APPLICATION B. REVISION TO SCREENING PROGRAM C. RENEWAL OF SCREENING PROGRAM CT CARDIAC □ CT COLON □ CT LUNG INDICATE WHICH SELF-REFERRAL SCREENING PROGRAM(S) 	 FACILITY NAME AND MAILING ADDRESS OF APPLICANT 2A. REGISTRATION NUMBER: 				
3.	SCREENING SITE NAME (If different from facility) AND ADDRESS WHERE SELF-REFERRAL SCREENING WILL BE PERFORMED	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION, TITLE AND EMAIL ADDRESS				
		4A. PHONE NUMBER:				
SUE TO	SUBMIT APPLICATION AND ITEMS 5. THROUGH 18. ELECTRONICALLY TO https://health.xray@state.mn.us . THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE COMPUTED TOMOGRAPHY SCREENING APPLICATION GUIDE.					
5.	PURPOSE(S) FOR THE SCREENING PROGRAM	6. DETAILED DESCRIPTION OF THE X-RAY EXAMINATION, FACILITIES, AND EQUIPMENT				
7.	DETAILED DESCRIPTION OF POPULATION EXAMINED	8. EVALUATION OF ALTERNATIVE METHODS				
9.	EQUIPMENT PERFORMANCE EVALUATION OF A DIAGNOSTIC RADIOLOGICAL PHYSICIST	10. MEASUREMENT OF PATIENT EXPOSURES FOR SCREENING EXAMINATION				
11.	DESCRIPTION OF QUALITY ASSURANCE PROGRAM	12. TECHNIQUE CHART FOR X-RAY EXAMINATION				
13.	QUALIFICATIONS OF INDIVIDUALS PERFORMING THE EXAMINATION	14. QUALIFICATIONS OF INDIVIDUAL SUPERVISING				
15.	QUALIFICATIONS OF INTERPRETING PHYSICIANS	16. PROCEDURE FOR INFORMING INDIVIDUALS SCREENED ANI THEIR PRIVATE PRACTITIONER				
17.	PROCEDURE FOR RETENTION OF IMAGES AQUIRED	18. FREQUENCY FOR SCREENING PATIENTS				
19.	 19. THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. NOTE: YOU MUST NOTIFY THE MINNESOTA DEPARTMENT OF HEALTH OF ANY CHANGE TO YOUR SELF-REFERRAL SCREENING PROGRAM THAT OCCURS DURING THE AUTHORIZATION PERIOD PRIOR TO IMPLEMENTATION. IF YOU WISH TO CONTINUE SCREENING AFTER THE APPROVAL END DATE, YOU MUST SUBMIT YOUR RENEWAL TO MINNESTOA DEPARTMENT OF HEALTH 30 DAYS BEFORE THE EXPLOATION DATE. 					
AD	MINISTRATOR'S NAME AND TITLE	PHONE NUMBER DATE				

APPENDIX B MODEL PROGRAM FOR MAINTAINING RADIATION EXPOSURE ALARA (4732.0530)

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program published in Appendix B to the MDH Regulatory Guide for Self-Referral Screening Procedures."

If you prefer, you may develop your own ALARA program for MDH review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed an ALARA program for your review that is appended as Appendix B," and submit your program.

ALARA PROGRAM

Management Commitment

We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a radiation safety officer.

We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past exposures dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing the changes.

In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

Annual review

The registrant and/or the radiation safety officer will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

The registrant and/or the RSO will review at least quarterly the radiation doses of the workers to determine that the doses are ALARA in accordance with the policy.

Education responsibilities for ALARA program

The RSO will schedule briefing and educational sessions as needed to ensure that the workers and other personnel who may be exposed to radiation are instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

Cooperative efforts for development of ALARA procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow to maintain the ALARA philosophy.

The RSO will be in close contact with the workers in order to develop ALARA procedures for working with radiation-producing equipment.

The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.

Workers will be instructed in recourses available if they feel that ALARA is not being promoted and supported on the job.

Reviewing instances of deviation from good ALARA practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

Registrant's responsibility to supervised individuals

The registrant will explain the ALARA concept and the need to maintain exposures as low as reasonably achievable to all staff.

The registrant will ensure that the supervised individuals who are subject to occupational radiation exposure are trained and educated in safe radiation practices involving time, distance, shielding, and appropriate techniques in maintaining exposures ALARA.

Documentation of training must be available onsite at each registered location, either in electronic or hard copy.

• Training records must include site specific and modality specific: date of training, topics covered and names/signature of trained individuals

APPENDIX C SUGGESTED CT ANNUAL AUDIT CHECKLIST (<u>4732.0540</u>)

Audit History	<u>4732.0540</u>	N/A	Yes	No
Date of the previous audit:				
Were previous audits conducted annually?	4732.0540			
Are records of previous audits maintained?	4732.0540			
Deficiencies identified?	4732.0540			
Were the deficiencies corrected?	4732.0540			
Have all records been maintained?	4732.0330			
Organization and Scope of Program		N/A	Yes	No
Is the Radiation Safety Officer identified?	4732.0500			
Does the RSO meet MDH training requirements?	4732.0500			
Is RSO fulfilling all duties?	4732.0505			
Is the written agreement in place for the RSO?	4732.0500			
All x-ray equipment registered with the MDH?	4732.0200			
Changes in program since the last audit?	4732.0520			
Operating and Emergency Procedures		N/A	Yes	No
Are the procedures current?	4732.0520			
ALARA program?	4732.0530			
Technique charts completed and in place?	4732.0550			
Holding procedures in place?	4732.0510			
Garments monitored for integrity?	4732.0550			
Orders include all required information?	4732.0560			
Provisions for declared pregnant staff?	4732.0415			
Individual Monitoring Device		N/A	Yes	No
Are individual monitoring devices in use?	4732.0440			
Users notified in writing of annual exposure?	4732.0440			
Reports maintained for 30 years?	4732.0440			
Is the monitoring worn in the proper locations?	4732.0440			

Shielding Plan				N/A	Yes	No
Shielding plan documentation	on?	4	4732.0355			
Shielding plan submitted for	r new or remodeled construction	n? 4	4732.0360			
Permanent placards?		4	4732.0360			
Radiation survey? (change i	in facility or equipment)	4	4732.0860			
Retake/Reject Analysis	S			N/A	Yes	No
Retake analysis written proc	cedure?	4	4732.0535			
Reasons listed for rejected s	studies?	4	4732.0535			
Repeat rate calculated quart	erly?	4	4732.0535			
Include the quarterly ana	lysis on annual audit?	4	4732.0535			
1 st quarter:	2 nd quarter:	3^{rd} qu	uarter:	4 th quart	er:	
Computed Tomograph	ny Requirements			N/A	Yes	No
Visual control of all entranc	es?	4	4732.0355			
2-way audio communication	n?	4	4732.0860			
Quality Control procedures	in place?	4	4732.0860			
CT unit daily QA quarterly	review?	4	4732.0860			
Laser film printer QC daily		4	4732.1100	L		
Equipment evaluations (EPI	E) performed within 12 months	? 4	4732.0860/4732.1100			
EPE performed after tube re	eplacement or installation?	4	4/32.0860/4/32.1100			
Utilization log maintained a	ind complete?	4	4/32.0545			
Computed Tomograph	ny Self-Referred Screenin	g		N/A	Yes	No
CT screening approved by M	MDH?	4	4732.0565			
Renewal submitted 30 days prior to expiration?			4732.0565			
CT screening revisions submitted to MDH?			4732.0565			
X-ray Operator Training				N/A	Yes	No
X-ray operators qualified?	4	4732.0580				
New x-ray operators receive	4	4732.0510/4732.0860				
Training program implemented?			4732.0510/4732.0860			
Operating procedures?			4732.0510			
Emergency procedures?		4	4732.0510			

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Training for changes in program? (new scanner/software change)	4732.0510		
Audits and Findings			
Summary of findings:			
Corrective and preventive actions:			
Comments:			
Audit conducted by:	Dat	e:	

APPENDIX D DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO) (4732.0505)

The RSO's duties and responsibilities include ensuring radiological safety and compliance with both MDH rules and the conditions of the radiation safety/quality assurance program. Typically, the RSO's duties and responsibilities include ensuring the following:

RSO Duties and Responsibilities				
Establish a quality assurance program	Radiation exposures are ALARA			
Identifying radiation protection problems	Development, maintenance, and implementation of up-to-date operating and emergency procedures			
Stopping unsafe activities using x-ray equipment	Ensure initial site specific training has been performed for safe operating procedures, emergency procedures and quality control procedures			
Ensuring compliance with regulations	Quality assurance program audits are performed at intervals not to exceed 12 months and development, implement, and documentation of timely corrective actions			



Radiation Control, X-ray Unit 625 North Robert Street PO Box 64497 St. Paul, Minnesota 55164-0497 651-201-4545 health.xray@state.mn.us www.health.state.mn.us/xray

DELEGATION OF AUTHORITY FOR A RADIATION SAFETY OFFICER (RSO) FOR AN X-RAY FACILITY (Please retain for your records)

Facility Name: _____

Facility Registration Number: _____

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, ______, have been appointed Radiation Safety Officer for our x-ray department. You are responsible for ensuring the safe use of radiation. Your responsibilities include managing the radiation protection program, identifying x-ray radiation protection problems, ensuring quality control tests are completed and documented, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with state regulations.

You are hereby delegated the time and authority necessary to meet those responsibilities, including prohibiting the use of radiation-producing equipment by employees who do not meet the necessary requirements and shutting down operations where radiation safety is compromised. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Minnesota Department of Health at any time.

It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Your signature below indicates acceptance of the above responsibilities.

Name of Radiation Safety Officer	Name of Management Representative
Signature of Radiation Safety Officer	Signature of Management Representative
Date	Date

cc: Department Heads MDH Self-Referral CT Screening Application Guide

APPENDIX E MODEL TRAINING PROGRAM (<u>4732.0510</u>)

Model procedures for describing training programs appear below. This model provides assistance to requirements for site specific training according to 4732.0510.

Facility Specific Training

In addition to meeting the initial qualifications for operators of x-ray equipment each operator must be instructed initially in site-specific and system specific procedures including:

- 1. Safe operating procedures to include patient holding
- 2. If applicable, restrictions of the operating technique required for the safe operation of the particular system
- 3. Emergency procedures
- 4. Quality control procedures
- 5. The use of proper protective shielding (when necessary)
- 6. Self-referral screening program
- 7. Additional training must be conducted at the time of any change to the quality assurance program or change in radiation output. Examples include, but are not limited to:
 - Replacement of or addition of a new CT unit
 - Change in the system that may affect the patient dose
 - Additional software changes

Training requirements for students, float staff, externs and temporary staff:

- 1. Students, externs, and float staff are required to perform the initial training at only one location if they remain within a system that has an established radiation safety/quality assurance program for all sites
- 2. Students and externs who train within different practices must receive training at each location of practice
- 3. Temporary staff working within different practices must receive training at each location of practice
- 4. Staff rotating between different locations must have system specific procedures training for different scanners at each location

Record Retention (Training)

- 1. Documentation of training must be available on site
- 2. Training records must include (site specific and modality specific):
 - Date of training
 - Topics covered
 - Signature of trained individuals

Online Training

MDH allows a variety of instructional methods, including on-line training, as acceptable for satisfying the classroom and laboratory portion of the Training and Experience (T&E) requirements, as long as the training meets the specific requirements and the subject matter relates to radiation safety and safe operating uses for operating radiation producing equipment.

MDH does not review or evaluate the training program themselves, nor does MDH endorse or approve the programs. Rather, it is the documentation of the T&E for each individual performing ionizing radiation.

APPENDIX F MODEL CT REPEAT/REJECT ANALYSIS PROGRAM (4732.0535)

Computed Tomography (CT) has been shown to be the source of the majority of radiation dose to the medical patient population. The use of CT scanning has increased dramatically in recent years according to NCRP Report No. 160. Analysis of repeated radiological images is an established method in assisting with reduction of undesired radiation dose to the patient. The expansion of this quality control method to include CT scanning is a necessary, although certainly not sufficient, means of reducing unwanted patient dose. The nature of CT scanning varies significantly from radiography and these differences should be taken into account when developing a program for managing repeat examinations in CT.

Probably the most significant difference is that CT as practiced today uses volume imaging rather than planar imaging. In early CT practice individual "slices" were obtained one at a time, similar in process to obtaining individual radiographs. In current practice, an entire volume is scanned, often in a single motion, and images are reconstructed sometimes at multiple slice thicknesses using varying image processing techniques. Because of this, the number of images bears no direct relationship to the amount of radiation used. Due to the speed of the scanning process, the most meaningful "unit" of the current CT scanning process has become the CT "series", with a potential to have one or more series per examination. (e.g., abdomen pelvis may contain an initial series with contrast and a separate series containing delays of just the pelvic region.)

The practice of performing CT imaging varies widely throughout the medical community, particularly between small and large institutions, both in number and complexity of exam protocols. In order for repeat analysis to be effective, it should be simple, risk-based and standardized to the point where a reasonable rate can be determined within all institutions.

The following guidelines are recommended for a standardized method of analyzing repeats in CT scanning and the associated radiation dose.

The CT repeat rate should be defined as:

CT Repeat Rate = Total Number of Repeated Series/Total Number of Series

OR

CT Repeat Rate = Total Number of Repeated Examinations/Total Number of Examinations

Implementation: The technologist records each of the repeated series within the examination (can be multiple per exam). The total number of series will be recorded by technologist for each examination performed. Or for larger institutions, it may be less complex to record examinations repeated and divide the repeated examinations into the total amount examinations performed. Topogram/scout images should be excluded from the analysis based on their extremely low dose compared to a series or examination.

In addition to documenting repeated imaging, an analysis of the examination must be performed on a quarterly basis and reviewed on your annual review of your program.

Rather than defining repeat "categories", the following preliminary list of repeat causes should be used as a guideline in repeat analysis:

Item	Notes/Comments
Artifact	Streaks, rings, contrast leakage, jewelry, anything the scanner put in the image that is not in the patient
Scanner malfunction/down	
Incorrect labeling	
Positioning	
Wrong side/wrong exam	
Insufficient technique	Needed higher mAs. Higher mAs available but not used
Motion	
Poor circulation time	Contrast never "peaked out" and scan was not diagnostic
Respiratory gating problem	ECG leads not functioning properly
Residual contrast	
Wrong injection rate	
Wrong injection site	Ex: right arm instead of left arm
Infiltrate	
Oral contrast concern	
Injector failure	
Contrast sensitivity	

APPENDIX G MODEL TECHNIQUE CHART (4732.0565)

		Primary Scanner			Secondary Scanner	
CT Screening	Siemens- Definition Flash	Siemens- Definition Flash	Siemens- Definition Flash	GE- LightSpeed	GE- LightSpeed	GE- LightSpeed
Detector Configuration	128	128	128	64	64	64
Patient Orientation						
Scan Acquisition						
Rotation Time(s)						
Collimation						
Pitch						
Scan Interval (mm)						
kVp						
Effective mAs or mA						
AEC mode - (on/off)	Care 4D (on/off)	Care 4D - (on/off)	Care 4D (on/off)	Smart mA (on/off)	Smart mA (on/off)	Smart mA (on/off)
Scan Width (mm)						
Scan FOV (cm)						
Display FOV (cm)						
CTDI-vol (mGy)						
Gated						
Dose Reduction Software	IRIS	IRIS	IRIS	ASiR	ASiR	ASiR
Imaging Area	Cardiac	Lung	Colon	Cardiac	Lung	Colon
Additional Information:						
Performed by:	Name:				Date:	

SUMMARY OF REVISIONS

Date	Revision	Section	Description
01/23/15	Revision 1		Document was redesigned and all content was revised