Conference of Radiation Control Program Directors, Inc.

NEWSBRIEF

www.crcpd.org A Partnership Dedicated to Radiation Protection February 2023

FROM THE CHAIRPERSON

CRCPD INITIATIVES & SUCCESSES

By Patrick Mulligan

The continued success of CRCPD depends on the active support of our members. **Many of you willingly volunteer to serve the CRCPD in a variety of roles including on the Board of Directors, as working group or task force members or as liaisons to our partner organizations**. I truly appreciate the continued dedication and support we get from all of you to help us reach the goals and objectives that support our primary mission. You provide the knowledge, skills, and abilities to help shape the future of radiation protection not just at a national level, but globally. CRCPD continues to be actively engaged by the international community to serve on a variety of working groups and panels. **I am always very impressed with the invitations CRCPD receives to help support radiation protection in the international community.** That is a tribute to your knowledge and experience and demonstrates the respect that you garner for our organization worldwide. Your continued willingness to volunteer at home and abroad are greatly appreciated. Just a few noteworthy international initiatives that CRCPD supports are presented in this article.

MEMBER CONTRIBUTIONS TO CRCPD SUCCESS

"I truly appreciate the continued dedication and support we get from all of you to help us reach the goals and objectives that support our primary mission."

Patrick Mulligan

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FROM THE CHAIRPERSON
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International Initiatives

- Ongoing collaboration with International Atomic Energy Agency (IAEA) thought the Practical Arrangement that was renewed late last year
- Participation in the revision of IAEA Safety Standards Report
- Representations at the IAEA Topical Session on Radiation Safety of Nonfood Commodities
- Invitation to support the European Regional Baltic Sea States (BSS) Workshop on the Management of Existing Radiation Exposure Situations
- Invitation to support the African Regional BSS Workshop on radiation protection and safety in the management of existing exposure situations
- Invitation to support the 16th International Radiation Protection Association Congress (IRPA-16) in 2024

Federal Partners

I recently had the opportunity to travel to Washington, D.C. and represent CRCPD at the annual visits with our federal partners. I was joined by Ruth McBurney, Executive Director; Angela Leek, Past-Chair; and Rikki Waller, Chair-Elect. We had a series of nine meetings over a four-day period. I find these meetings to be incredibly valuable. **We have the opportunity to review what we have accomplished over the past year, discuss our goals and objectives, and plan for ongoing and future collaborative activities.** Like our volunteers, our federal partners are another key component to the continued success and growth of the CRCPD. A few highlights from our discussions with our federal partners are given in this article.

FEDERAL PARTNERS' CONTRIBUTIONS TO CRCPD SUCCESS

"Like our volunteers, our federal partners are another key component to the continued success and growth of the CRCPD."

Patrick Mulligan

FROM THE CHAIRPERSON
(continued)

US Department of Transportation (DOT)

At the meeting with DOT, we were able to provide a draft of the draft electronic Special Permit form developed by the collaborative effort of the E-34 and E-48 Committees. We asked for DOT for their comments and input. We also discussed issues and concerns of state programs regarding with tracking "misplaced" packages in transit with common carriers. **DOT does appreciate the concerns that state radiation control programs have with shipments of materials that become misplaced while being transported.** DOT agreed to assist where they can with tracking these packages. Email contacts will be sent to CRCPD program directors to provide to appropriate staff.

US Nulcear Regulatory Commission (NRC)

NRC senior leadership provided CRCPD with updates on the status of pending rulemaking decisions including Emergency Preparedness (EP) for small modular reactors, the decommissioning rule, Part 53 on Advanced Reactors, and the Category 3 Source Security rule. All of these rules are with the commission for consideration. NRC also provided information on how they prioritize rulemaking and that the prioritization list is available on the NRC web site. Rulemaking priorities are set on an annual basis based on staff input and are adjusted throughout the year, if necessary. NRC welcomes opportunities to get state input to the process. The Organization of Agreement States (OAS) has representation in working groups that address rulemaking and their input can help set rulemaking priorities. We provided some thoughts to NRC on the topics that will be covered at the CRCPD/OAS Commission briefing in May 2023.

NRC RULEMAKING

"Rulemaking priorities are set on an annual basis based on staff input and are adjusted throughout the year, if necessary. "

Patrick Mulligan

Department of Homeland Security/ Federal Emergency Management (DHS/FEMA)

FEMA senior leadership provided an overview of the re-organization that will better align the prevention, response, and emerging threat programs. Public communication is a topic that is high on the list of priorities for the organization. **They are looking for opportunities to develop lists of Subject Matter Experts that can discuss radiological concerns at a level suitable for the general public.** FEMA is considering putting together a multi-agency working group to address public communications. We offered to support this initiative and informed FEMA that CRCPD has working groups that actively work on public messaging for radiological emergencies. **The future of the Radiological Operations Support Specialist (ROSS) program was also discussed at length during the meeting.** CRCPD recognizes that a mechanism is necessary to support the ongoing maintenance and administration needs of the program to ensure its continued success. There was discussion about creating a sub-committee of the Federal Radiological Preparedness Coordinating Committee (FRPCC) as a means to manage and fund the maintenance and administration of the ROSS program. CRCPD has been provided an opportunity to address the Federal Radiological Monitoring and Assessment Center (FRMAC) in March on this topic.

US Environmental Protection Agency (EPA)

Among a list of topics covered at the EPA meeting was a proposed framework for radon Credentialing Criteria for testers and mitigators and the development of a SharePoint storage capability for warehousing data and resources.

FEMA PUBLIC COMMUNICATION PRIORITY

"We offered to support this initiative and informed FEMA that CRCPD has working groups that actively work on public messaging for radiological emergencies."

Patrick Mulligan

FROM THE CHAIRPERSON
(continued)

EPA - continued

There was discussion regarding a review and revision of SSR Part N to reflect TENORM standards. Some time was spent on discussing lab capabilities for emergency response. All recognized the difficulty to get a firm handle on the exact national capabilities of the lab network. Often, assets are counted in two or three separate networks and others become unavailable if personnel are assigned to other tasks. EPA is now the Chair of the Advisory Team and plans to meet in March. CRCPD will attend the Advisory Team meeting and provide an update on initiatives related to emergency preparedness and response.

US Department of Energy (DOE)

CRCPD works very closely with DOE on source recovery issues and activities. This has been a very successful partnership to collect and commercially dispose of sealed sources no longer in use, which could individually or in aggregate be used maliciously. Over the past year, DOE has worked to resolve the issue with availability of casks used for the disposition of larger sources. More casks have become available so that the Source Collection and Threat Reduction (SCATR) and Cesium Irradiator Replacement Project (CIRP) may move forward without delays. **About 50% of the cesium sources identified under CIRP have been disposed, and DOE is looking for assistance with outreach to sites that might participate in the program and replace cesium sources with new technology.**

DOE SOURCE RECOVERY ACTIVITIES

"This has been a very successful partnership to collect and commercially dispose of sealed sources no longer in use, which could individually or in aggregate be used maliciously."

Patrick Mulligan

DOE - continued

DOE is also re-evaluating the integration of FRMAC into the Industrial Control Systems (ICS) structure and looking for opportunities to improve that process. **DOE is also the evaluating Radiological Assistance Program Training for Emergency Response (RAPTER) modules and are looking to develop training standards and proficiency testing to ensure consistency across all RAP regions.**

RadResponder Contract

During our federal visits, we learned from DHS/FEMA that the contract with Chainbridge for CBRNResponder expires this year and there will be another contract bid going out. US Treasury has a requirement that this contract is awarded to an 8A small business entity. Chainbridge has grown over the past nine years that they have been under contract and may no longer qualify to bid on this contract. It is possible that the contract will be awarded to company other than Chainbridge. **With the level of commitment states and other organizations have made to incorporating RadResponder into plans, procedures and response activities, there is great concern whether a new start up small business can provide the level of service that the EP community has become accustomed to for so many years with Chainbridge**. CRCPD is drafting a letter to FEMA outlining our concerns.

CBRNRESPONDER CONTRACT

"During our federal visits, we learned from DHS/FEMA that the contract with Chainbridge for CBRNResponder expires this year and there will be another contract bid going out."

Patrick Mulligan

FROM THE CHAIRPERSON
(continued)

CRCPD Support for the Organization of Agreement States (OAS) Spring Board Meeting

CRCPD has been invited to participate in the Annual OAS Spring Board meeting to provide an update on activities. Rikki Waller, Chair-Elect, has agree to attend the meeting on March 8.

As you can see there is always so much going on within the CRCPD. Some weeks I have a hard time keeping up with all the activity. It is truly a rewarding experience to be a part of this great organization. **Of course, as I stated in the beginning, none of this is possible without the continued support from all of you.**

If there is ever something you need from us which you are not getting, please do not hesitate to reach out to one or more Board members or to the Office of Executive Director and let us know.

CRCPD ASSISTANCE TO MEMBERS

"If there is ever something you need from us which you are not getting, please do not hesitate to reach out to one or more Board members or to the Office of Executive Director and let us know."

Patrick Mulligan

EXECUTIVE DIRECTOR'S MESSAGE

A BUSY START TO 2023, AND GOOD THINGS TO COME!

by Ruth McBurney, CHP

The new year has gotten off to a very busy start at CRCPD. The Board and committees have been quite active and are creating great tools and resources for the radiation control programs, addressing new radiation protection issues through collaboration with federal and international partners, and planning our upcoming National Conference on Radiation Control.

The Office of the Executive Director (OED) staff likewise have been carrying out a lot of behind-the- scenes work on getting ready for the Annual Conference, providing materials for our annual audit, and applying for two major federal cooperative agreements.

I am pleased to provide some of the highlights of the last couple of months and plans for some upcoming events.

Visits to Federal Agencies

In late January, the Board leadership, consisting of the Chairperson, Chair-Elect, Past Chair, and I visited with several federal agencies and organizations that are headquartered in the Washington, DC area. **Several great ideas for future collaboration came out of those meetings, to the benefit of state and local radiation control programs.**

A VERY BUSY START!

" The Board and committees have been quite active and are creating great tools and resources for the radiation control programs, addressing new radiation protection issues through collaboration with federal and international partners, and planning our upcoming National Conference on Radiation Control."

Ruth McBurney

EXECUTIVE DIRECTOR'S MESSAGE
(continued)

A BUSY START TO 2023, AND GOOD THINGS TO COME!

Surveys—A Way to Gather Information from the State Programs

It seems that recently, more than ever, there has been a lot of interest in how the states handle certain issues, policies and rulemaking, as well as training needs and emergency response capabilities. **At the request of committees working on various issues such as suggested state regulations, policy changes for gonadal shielding, training for state radiation control personnel, and emergency response planning, we frequently send out surveys to the state radiation control programs for input on those topics.**

Other organizations also are interested in how the states approach these topics as well. For implementation of the changes in gonadal shielding guidance, for example, the American College of Radiology is sharing this information on their website and will be providing a link that we will put on our website as well. The surveys we do on training needs, such as laser technology and regulation, have helped us determine subjects for short training sessions at the National Conference and webinars.

The results of our most recent survey on the use of the Suggested State Regulations and involvement of advisory boards and other stakeholders will be sent to the program directors and are available to other groups on request.

We encourage you to participate in these surveys, since they provide the "big picture" of the status of the programs and how their approach to regulatory issues.

SURVEYS OF STATE RADIATION CONTROL PROGRAM

" The surveys we do on training needs, such as laser technology and regulation, have helped us determine subjects for short training sessions at the National Conference and webinars."

Ruth McBurney

EXECUTIVE DIRECTOR'S MESSAGE *(continued)*

A BUSY START TO 2023, AND GOOD THINGS TO COME!

Practical Arrangement with the International Atomic Energy Agency (IAEA)

In October 2022, CRCPD extended its Practical Arrangement with the IAEA and has been working with them to develop work plans for the scope of work, that being to work collaboratively in:

- **the development and sharing of information** that can improve radiation protection and safety in the area of naturally occurring radioactive materials (NORM) that can impact the environment, public and occupational workers.
- **the preparation of guidance and other relevant materials** (outreach materials, on-line courses, etc.) addressing radiation exposure where natural radiation, in particular radon, exists, including cooperation toward preparing an atlas of natural radiation.
- **radiation protection of patients**, especially in the area where new radiation source technologies used in medicine.
- **contaminated or radioactive materials** (including NORM and TENORM) containing non-food consumer goods or commodities.
- **preparation of guidance and other relevant materials** (outreach materials, on-line courses, etc.) addressing exposures from radionuclides in food in non-emergency situations.

Work on several of these areas has already begun, and we are looking forward to more interaction with IAEA in these areas, which will benefit both the radiation control programs in the US, but will also assist other countries as they contend with these issues. CRCPD has been requested to provide speakers for workshops in the Czech Republic and Zimbabwe on radiation in

IAEA & CRCPD INTERACTIONS

"The work will benefit both the radiation control programs in the US, but will also assist other countries as they contend with these issues."

Ruth McBurney

EXECUTIVE DIRECTOR'S MESSAGE *(continued)*

A BUSY START TO 2023, AND GOOD THINGS TO COME!

existing exposure situations, and to provide an expert to assist with standards for radon in the workplace. At the upcoming National Conference on Radiation Protection in May, we plan to have an interactive panel discussion among the project leaders from both IAEA and CRCPD to highlight some of the work, provide plans for the future, and seek input from the membership on our collaborative work.

Outreach and Training Planned for ISRI Safety and Environmental Conference

During the Board leadership visit with the Institute of Scrap Recycling Industries (ISRI) in Washington in January, **CRCPD agreed to provide a presentation or workshop at ISRI's upcoming Safety and Environmental Conference in May in St. Louis, MO.** We plan to send representatives to provide their organization with information on basic radiation detection in scrap, the types of materials to look for and what to do when they detect certain levels of radiation in a load; provide guidance on the use of the Department of Transportation Special Permit, and answer many of the frequently asked questions. This should be beneficial for furthering our work in radiation protection.

Support for IRPA-16 in 2024

CRCPD has been asked to be a supporter of the 16th International Radiation Protection Association Congress (IRPA-16), which will be held in Orlando, Florida, in July 2024. **This will be the first time in 51 years that the International Congress has been held in the United States and the first time since 1992 that it has been held in North America.**

CONTRIBUTING TO ISRI CONFERENCE

"We plan to send representatives to provide their organization with information on basic radiation detection in scrap, the types of materials to look for and what to do when they detect certain levels of radiation in a load; provide guidance on the use of the Department of Transportation Special Permit, and answer many of the frequently asked questions."

Ruth McBurney

EXECUTIVE DIRECTOR'S MESSAGE *(continued)*

A BUSY START TO 2023, AND GOOD THINGS TO COME!

Many of the topics of the Congress, the theme of which will be "'Radiation Harmonization: Standing United for Protection," should be of great interest to our membership. We have provided our logo in support of the congress, and CRCPD will be listed as one of the sponsors of IRPA-16.

Planning for the National Conference on Radiation Control

The agenda, hotel information, and registrations are now available on the CRCPD website for the upcoming **55th National Conference on Radiation Control (NCRC), to be held in Houston, TX, May 8-11, 2023.** We are also planning to provide **a two-day Mammography Educational Conference in conjunction with the NCRC.** More information and links on these two events are provided in separate articles in this issue of the Newsbrief. Make your plans to attend!

Also, we have established the dates for the **2024 NCRC, which will be held in Jacksonville, Florida, May 20-23, 2024. Mark your calendars for this one as well.**

I hope that at the pace we are moving, that 2023 will continue to be a very active year for the organization. **I encourage you to find an area to become involved—join a committee or encourage your staff to do so, make a presentation, or run for an office.** You will find that we are doing good not only for the individual state programs, but the country as a whole and internationally as well.

Hope to see you in Houston in May!

PLEASE JOIN US IN MAY!

55th National Conference on Radiation Control

(NCRC)

Houston, TX, May 8-11, 2023

AND

Two-day Mammography Educational Conference in conjunction with the NCRC

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YOU'RE INVITED!

55th National Conference on Radiation Control

The Conference of Radiation Control Program Directors invites you to join us for our 55th National Conference on Radiation Control in Houston, Texas, May 8 – 11, 2023.

Here you will find the official **Announcement and Invitation** which includes the tentative agenda, registration, and hotel information.

The best way to make your hotel reservations at the Omni Houston Hotel is by going directly to:

Omni Houston - CRCPD 55th National Conference on Radiation Control

If making your reservations by phone, we ask that you use our name **CRCPD 55th NATIONAL CONFERENCE ON RADIATION CONTROL**, so you will be included in our room block to help us meet our room commitment.

Please visit CRCPDAnnualMeeting.org for updates and more information.

Registration is now open!

We hope to see you in Houston, Texas!

Mammography Educational Conference

Friday & Saturday
May 5 & 6, 2023

YOU'RE INVITED!

Mammography Educational Conference

The Conference of Radiation Control Program Directors invites you to attend our Mammography Educational Conference in Houston, Texas, May 5 – 6, 2023.

You can find the tentative agenda, registration, and hotel information by visiting CRCPD Mammo Educational Conference.

Please help us meet our guest room block by making your hotel reservations at the Omni Houston Hotel by going directly to:

Omni Houston - CRCPD Mammography Educational Conference

Registration is now open!

PARTNERS: US FOOD AND DRUG ADMINISTRATION

FDA PUBLISHES FINAL RULE FOR AMENDMENTS TO THE RADIOLOGICAL HEALTH REGULATIONS AFFECTING SUBMITTAL OF FDA FORM 2579

January 20, 2023, the U.S. Food and Drug Administration (FDA) published the final rule:

> *Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser and Ultrasonic Products.* See the *Federal Register* publication at this link.

Facts about the Final Rule

The final rule amends and repeals parts of the radiological health regulations, including to:

- Remove recommendations in the regulations that have become outdated or duplicative to more current FDA, industry, and professional society recommendations;
- Amend and repeal certain records and reporting requirements for electronic products, including reporting for diagnostic x-ray systems and lasers that are unnecessary or duplicative of other reporting requirements by the FDA; and
- Amend the reporting requirements for manufacturers that incorporate a certified Class I, II, IIIa laser product to reduce reporting that is considered duplicative under certain conditions.

In this rulemaking, FDA is removing the requirement to submit a copy of Form FDA 2579 (Report of Assembly of a Diagnostic X-Ray System) to FDA. Assemblers will still be required to submit a copy to the purchaser, and, where applicable, to state agencies responsible for radiation protection. For the downloadable fillable form and the state agency contact directory see the CRCPD website at this link.

Assemblers, including manufacturers who are assembling diagnostic x-ray equipment, subject to the provisions of § 1020.30(d) will still be required to maintain a copy of the report of assembly for 5 years.

The effective date for the final rule is 30 days following publication in the Federal Register. On the effective date of the final rule, FDA intends to update a number of CDRH guidances and web pages to reflect these changes to the radiological health regulations.

If you have questions about this final rule, contact the Radiological Health Program at RadHealth@fda.hhs.gov.

Donald L. Miller, M.D., FSIR FACR
Chief Medical Officer, CDRH FDA

FDA'S REGULATIONS FOR LABELING OF X-RAY DEVICES

Introduction

Inspectors may come across x-ray devices where there is a concern that the device has not been cleared or approved for use by the Food and Drug Administration (FDA). Reports to FDA from several states suggest that is most common with handheld dental x-ray systems. Regardless of the x-ray system, in these situations one way to make this determination is to inspect the device for FDA-required labels. If these are required but are not present, or are not as specified in FDA's regulations, or are not located as specified in those regulations, it is highly unlikely that the device has been introduced into commerce legally. The purpose of this article is to clarify and explain FDA's regulations for labeling of x-ray devices. The labeling requirements are summarized in Table 1 and further explained in this article.

Prescription and Medical Devices

For prescription medical devices, a group that includes all x-ray devices used in medical, dental, and veterinary imaging, a label with the symbol statement "Rx only" or "Px only" or the statement "Caution: Federal law restricts this device to sale by or on the order of a ___" (the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices) is one of the conditions (21 CFR 801.109) that allows the device to be exempted from the requirements of section 201(m) of the Federal Food Drug and Cosmetic Act. This label is therefore commonly found on these devices (Fig. 1).

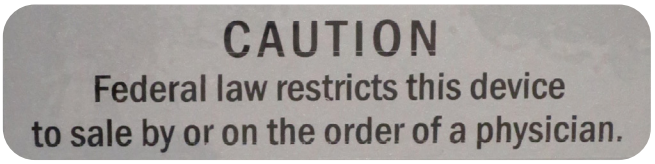

Figure 1.

FDA'S REGULATIONS FOR LABELING OF X-RAY DEVICES - continued

FDA's other labelling requirements derive from the electronic product radiation control provisions in Title 21 Code of Federal Regulations Subchapter J (21 CFR 1000-1050). These apply to medical and veterinary x-ray systems as electronic products and emit electronic product radiation, as defined in 21 CFR 1000.3(j) and 21 CFR 1000.3(k). Definitions are lengthy and are not included here.

The labeling requirements in 21 CFR 1000-1050 apply to medical, veterinary, industrial, and all other electronic products that emit x-rays, but differ for different kinds of x-ray devices and on the device's intended use (e.g., human or animal). FDA has issued specific performance standards for certain kinds of x-ray devices intended for use on humans. These include diagnostic x-ray systems (x-ray systems designed for irradiation of any part of the human body for the purpose of diagnosis or visualization) and their major components (21 CFR 1020.30), radiographic equipment (21 CFR 1020.31), fluoroscopy equipment (21 CFR 1020.32), and computed tomography (CT) equipment (21 CFR 1020.33). As discussed in this article, there are also medical x-ray systems intended for use on humans that are not regulated as diagnostic x-ray systems. These are primarily radiation therapy and veterinary systems.

There is also a performance standard for cabinet x-ray systems (21 CFR 1020.40). Cabinet x-ray systems have the x-ray tube installed in an enclosure, called a cabinet, designed to attenuate radiation and keep people out (21 CFR 1020.40(b)(3)). The x-ray systems used to screen carry-on bags at the airport are an example of a cabinet x-ray system. There are specific warning label requirements for cabinet x-ray systems illustrated in this article.

All x-ray systems for which a performance standard exists must have certification, identification, and warning labels. These labels must be permanently affixed or inscribed on the product so that they are legible and readily accessible to view when the product is fully assembled for use. The labels must be in the English language. Since there is a performance standard for diagnostic x-ray systems intended for use on humans, the requirement for certification, identification, and warning labels applies to all of these x-ray systems. It also applies to cabinet x-ray systems because there is a performance standard for these systems, but it does not apply to other x-ray systems, such as those for veterinary, analytical, or industrial use systems that do not include a shielded cabinet.

The requirements for certification and identification labels are the same for diagnostic x-ray systems and cabinet x-ray systems, but the requirements for warning labels differ. The certification label (21 CFR 1010.2) certifies that the product conforms to all applicable performance standards (Fig. 2, 2A) shown on the following page.

FDA'S REGULATIONS FOR LABELING OF X-RAY DEVICES - continued

Figure 2.

No specific wording of the label is required. In most cases, certification labels are also required for each certifiable component of a diagnostic x-ray system (Fig. 3).

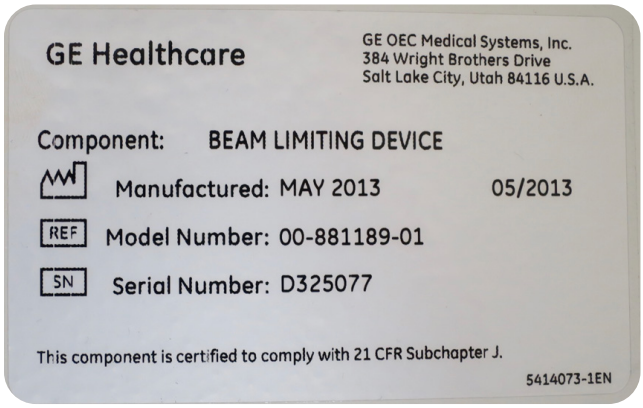

Figure 3.

These certifiable components are listed in 21 CFR 1020.30(a)(1) for diagnostic x-ray systems, and include, among others, tube housing assemblies, x-ray controls, generators, image receptors, and beam limiting devices.

The identification label (21 CFR 1010.3) must provide the full name and address of the manufacturer and the place and month and year of manufacture (Fig. 4).

Figure 4.

The place of manufacture may be expressed in code, but the month and year of manufacture must be provided clearly and legibly, without abbreviation, and the year must be shown as a four-digit number, worded as "MANUFACTURED: (MONTH YEAR). Internationally recognized symbols may be used instead for certain words, such as "manufacturer." Identification and certification labels are often combined (Figs. 4,5). See Figure 5 on the following page.

Figure 5.

(21 CFR 1020.30(j)) must be placed on the control panel containing the main power switch and must be legible and accessible to view (Fig. 6).

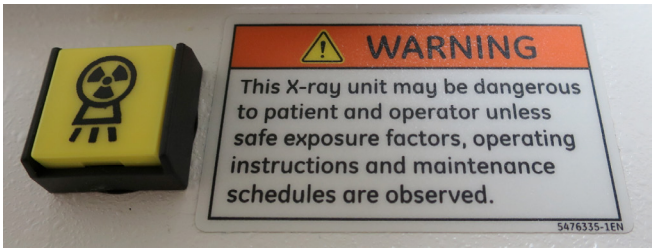

Figure 6.

Diagnostic X-ray Systems

The requirements for certification and identification labels are previously described in this article. There are additional identification labeling requirements for components of a diagnostic x-ray system. These components, with limited exceptions (21 CFR 1020.30(e)), must have identification labels that include the model and serial number. The specific word "model" or "type" must be included in the label. All tube housing assemblies must be labeled with the name of the manufacturer, model number, and serial number of the x-ray tube that the tube housing assembly incorporates, since x-ray tubes are subject to frequent replacement (21 CFR 1020.30(e)(1)). The warning label for diagnostic x-ray systems

The exact wording of the warning label is specified in the regulation and depends on the date of manufacture. For controls manufactured before June 10, 2006, the required wording is "Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed." For controls manufactured after that date the required wording is: "Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed." If a remote exposure switch is installed, the warning label and technique factors to be used before an exposure begins must be visible and legible from any position where the remote exposure switch is mounted, except in the case of spot films made by the fluoroscopist.

FDA'S REGULATIONS FOR LABELING OF X-RAY DEVICES - continued

Many newer diagnostic x-ray systems use a computer and display monitor to control the system instead of a control panel. FDA considers that a computer with an off-the-shelf monitor that uses software to control a diagnostic x-ray system serves the same function as an x-ray control. These computers and displays are subject to the same labeling requirements as any other diagnostic x-ray control as described in 21 CFR 1020.30(b). The certification and identification labels (or a display of their contents) must be readily accessible by the user and the required warning statement must be displayed on each computer with an off-the-shelf monitor used as a control panel (21 CFR 1020.30(j)). There are multiple ways to meet these labeling requirements. For example, physical labels consistent with 21 CFR 1010.2 (certification), 1010.3 (Identification), and 1020.30(j) (warning label) can be used. Alternatively, the labeling can be electronic (on the display monitor), so long as (1) each time the system is started, the screen displays the identification label and the certification label, requiring user action before removing these labels and resuming the start-up sequence and (2) during use, the required warning label is continuously displayed on the screen.

Cabinet X-ray Systems

In addition to the certification and identification labels described previously in this article, cabinet x-ray systems are required to have two warning labels (21 CFR 1020.40(c)(8)). Both labels must be clearly legible and visible, and permanently affixed or inscribed on the cabinet x-ray system. The first label must be placed at the location of any controls that can be used to initiate x-rays. The exact wording is specified in 21 CFR 1020.40(c)(8)(i): "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED." Cabinet x-ray systems may have one or more ports—openings in the outside surface of the cabinet intended to allow objects to be moved in or out of the cabinet and designed to remain open while x-rays are generated. (21 CFR 1020.40(b)(9) provides the precise definition of a port.) The second label must be placed adjacent to each port, with the exact wording (21 CFR 1020.40(c)(8)(ii)): "CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED—X-RAY HAZARD."

Other X-ray Systems

Other x-ray systems include both medical and non-medical systems. Medical x-ray systems include, but are not limited to, radiation therapy products that use x-ray tubes or particle accelerators and veterinary x-ray systems. Non-medical x-ray systems include analytical x-ray systems, industrial x-ray systems, ion implanters, electron beam welders, electron microscopes, and particle accelerator systems. There are no performance standards for veterinary, industrial or other x-ray or particle radiation equipment, so the electronic product radiation control provisions in Title 21 Code of Federal Regulations Subchapter J have no requirements for certification, identification, or warning labels for these products and therefore they do not need to have these labels.

Analytical x-ray systems are systems designed exclusively for the microscopic examination of material. The phrase "exclusively for the microscopic examination of material," refers to x-ray spectroscopy, x-ray diffraction, or x-ray fluorescence. These x-ray systems are usually intended to be operated only in a laboratory setting. An x-ray system is exempt from the performance standard for cabinet x-ray systems when it is designed exclusively for microscopic examination of material (21 CFR 1020.40(a)).

Industrial x-ray and particulate radiation systems are systems that are not subject to the cabinet x-ray or diagnostic x-ray standards, do not fall into the analytical x-ray or medical x-ray categories, and use x-ray tubes or accelerators to produce ionizing radiation. Examples of industrial x-ray systems include particle accelerators used for medical device sterilization, open beam systems used for nondestructive testing, open beam systems used for bomb detection, and personnel security screening systems that use x-rays. However, systems whose radiation source is an x-ray tube, that have an industrial purpose, and are closed systems (i.e., include a shielded cabinet) are cabinet x-ray systems and are subject to that performance standard.

Examples of Incorrect Labels

Labels that do not meet FDA requirements are one indication that the device may not have been cleared or approved by FDA. See the examples in Figures 7, 8, 9 and 10 on the following page.

FDA'S REGULATIONS FOR LABELING OF X-RAY DEVICES - continued

For example, the label may not be in English (Fig. 7).

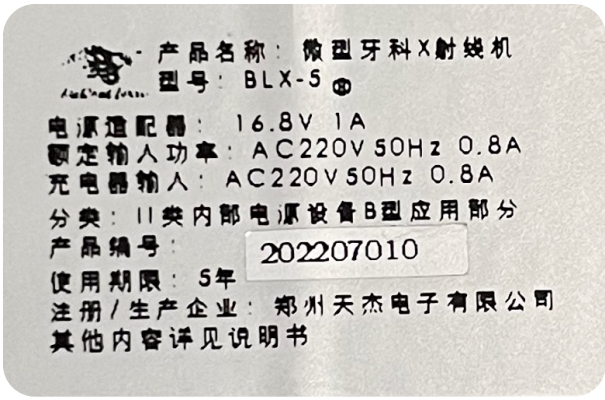

Figure 7.

The date may not be expressed correctly (Fig. 8).

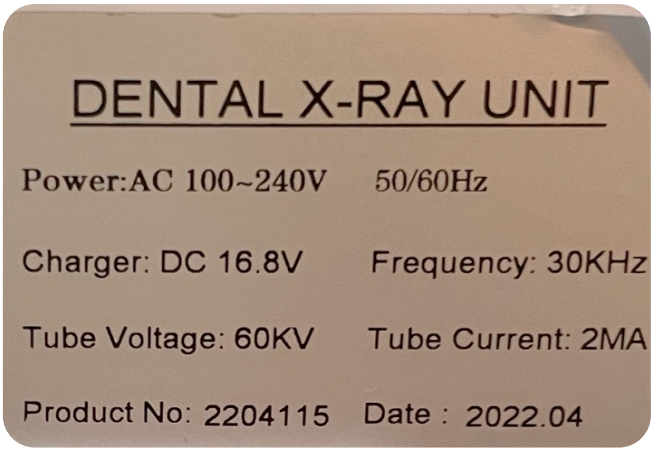

Figure 8.

Some or all of the necessary information may be missing, or there may be misspellings (Fig. 9).

Figure 9.

The label may not be clearly legible (Fig. 10).

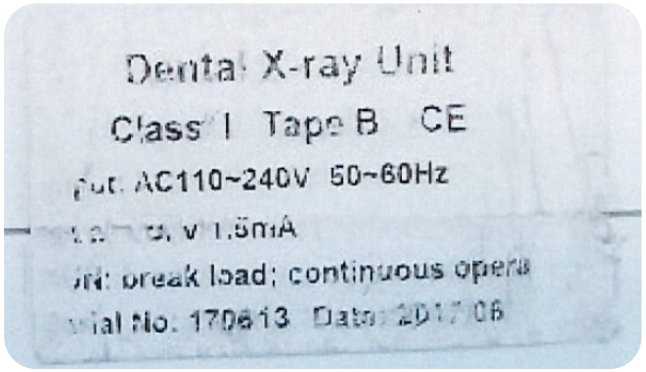

Figure 10.

Most commonly, one or more of the required labels is missing and the labels that are present do not meet the requirements for any of the required labels.

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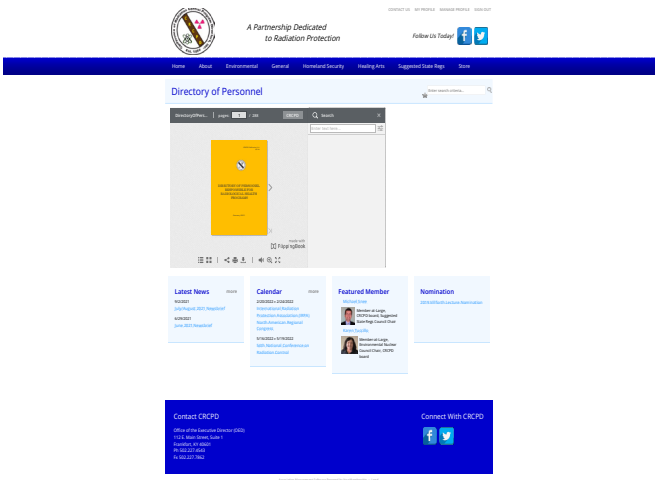

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CRCPD is interested in what you are doing and would like to share your knowledge and experiences with other CRCPD members through a feature article in the *Newsbrief*.

If you would like to submit an article, please contact Ruth McBurney (rmcburney@crcpd.org) suggesting a topic you'd like to present.

The *Newsbrief* is published six times a year, in even numbered months. Deadline for submission is the 15th of the month of publication.

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