August 29, 2014

MEMORANDUM TO: Chairman Macfarlane
Commissioner Svinicki
Commissioner Magwood
Commissioner Ostendorff

FROM: Brian E. Holian, Acting Director ***/RA/ RLorson for BHolian***
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: INTERNATIONAL PATIENT RELEASE PRACTICES FOLLOWING IODINE-131 THERAPY

The purpose of this memorandum is to provide information as requested by SRM-M140509, "Staff Requirements – Meeting with the Advisory Committee on the Medical Uses of Isotopes," where the Commission directed staff to provide information on the international patient release practices following iodine-131 therapy, especially focusing on countries with advanced medical systems.

Staff in the Office of Federal and State Materials and Environmental Management Programs, with assistance from the Office of International Programs, surveyed numerous countries regarding their patient release practices (Enclosure 1 provides a summary of the responses by country). Specifically, staff asked questions in the following areas:

1. The country's requirements or regulations for release of patients following the administration of iodine-131;

2. A description of the practice(s) for release of patients administered iodine-131 to include release to homes or hotels, or retention in an isolated hospital room or other location to reduce the exposure to families and members of the public;

3. The typical activity given to hyperthyroid patients and thyroid cancer patients per doctor visit; and

4. The date of latest revision to their requirements or regulations.

The U.S. Nuclear Regulatory Commission's (NRC) Title 10 *Code of Federal Regulations*, section 35.75, often referred to as the "Patient Release Rule," establishes the regulatory framework for releasing patients, who have been administered unsealed byproduct material or implants containing byproduct material, from licensee control.

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These regulations allow a licensee to authorize the release of a patient if the total effective dose equivalent to any other individual, from exposure to the released patient, is not likely to exceed 5 mSv (500 mrem). If the dose to an individual would exceed 5 mSv (500 mrem), the patient has to remain under licensee control. [Note: NRC has additional requirements to provide instructions to patients if a member of the public could receive 100 mrem.]

Seventeen countries responded to our survey. However, it was unclear as to whether the responses were provided by regulators, other government entities (i.e., similar to our State Department), or medical professionals. The data provides some information on international guidelines used in other countries.

All of the countries that responded to our survey follow patient release criteria based on activity and/or radiation field measurement criteria that are at or below the NRC's pre-1997 release criteria[1]. Eleven of the countries followed either the release guidance levels established by the International Atomic Energy Agency (IAEA) or the Heads of the European Radiological Protection Competent Authorities (HERCA).

In 1996, the IAEA published guidance for patient discharge from a hospital in "*The International Basic Safety Standards (BSS) for Protection Against Ionizing Radiation and for the Safety of Radiation Sources."* The 1996 BSS provided a guidance level for the maximum activity for patients in therapy requiring iodine-131 treatment of 1100 MBq (29.7 mCi) of iodine-131 for discharge from hospitals, which is essentially the same as the NRC's pre-1997 activity level criteria of 1110 MBq (30 mCi). IAEA's guidance also noted that some countries use 400 MBq (10.8 mCi) as a good practice. Bangladesh and Malaysia indicated that they generally adhere to the IAEA's guidance of 1100 MBq (29.7 mCi). While Canada and Taiwan do not have written regulations or requirements for the release of patients administered radioactive iodine, their medical communities voluntarily adhere to IAEA's guidance. China and Lithuania follow the good practice release guidance of 400 MBq (10.8 mCi). In addition, Lithuania typically hospitalizes its patients for three days.

HERCA was created in 2007 at the initiative of the French Nuclear Safety Authority. HERCA is a voluntary association that brings together 49 radiation protection Authorities from 31 European countries. HERCA published its guidelines in June 2010 on iodine-131 patient release criteria, recommending hospitalization for patients administered greater than 800 MBq (21.6 mCi) of iodine-131. Patients can be released from the hospital if both the dose rate emitted is less than or equal to 40 µSv/h (4 mrem/h) at 1 meter, *and* the patient is ready, willing and able to follow the recommendations and instructions provided by the physician. France, the United Kingdom, Poland, Spain, and New Zealand require that patients are not released until their retained activity has fallen below 800 MBq (21.6 mCi) in alignment with HERCA's published guidelines.

Germany, Australia, Japan, South Africa, and the Philippines' responses listed different guidelines. Germany does not permit discharge of patients until the patient has spent at least 48 hours in the hospital and has a local dose rate of less than or equal to 3.5 µSv/h (0.35 mrem/h) at 2 m or the retained activity has fallen below 250 MBq (6.8 mCi). Australia does not

[1] Prior to 1997, NRC regulations authorized the release of patients if (1) the measured dose rate from the patient was less than 50 µSv/h (5 mrem/h) at 1 meter or (2) the patient had a retained activity of 1110 MBq (30 mCi) or less.

permit the discharge of patients until the dose rate drops below 25 μSv/h (2.50 mrem/h) at 1 meter. Japan does not permit discharge until the retained activity has fallen below 500 MBq (13.5 mCi). South Africa does not permit discharge until the dose rate drops below 2.5 μSv/h (0.25 mrem/h) MBq (30 mCi) or less.at 1 meter. The Philippines does not permit discharge until the total effective dose equivalent is not likely to exceed 3 mSv (300 mrem).

For the treatment of thyroid cancer, the standard practice or protocol, both in the U.S. and abroad, is to prescribe up to 5550 MBq (150 mCi) of iodine-131. It is important to note that in the United States, before 1997, in order to immediately release patients, it was typical for patients to receive their therapy in multiple fractionated dosages of 1073 MBq (29 mCi) or less per fraction, so that they could be immediately released. However, that protocol was deemed to be less effective than receiving the full therapy as a single dosage. The data provided in response to the survey does not indicate if the radioactive iodine is administered as a single dosage or as multiple fractionated dosages, which would allow for the immediate release of the patient.

In 2009, IAEA published a technical document, IAEA-TECDOC-1608, "Nuclear Medicine in Thyroid Cancer Management: A Practice Approach", which states that although the 1996 BSS establishes guidance levels for release, a single model of release criteria would not be appropriate. It is recommended that the release of patients be individually determined and should not be linked only to residual activity in the patient, but should take into account many factors including the patient's pattern of contact with other persons, the patient's wishes, occupational and public exposures, family considerations, cost and environmental factors. It was also recommended that when there are many contiguous countries, a uniform or similar approach to releasing patients be developed. Similarly, in 2010, HERCA published "^{131}I therapy: Patient release criteria," which stated that specific situations may lead to the application of more severe release criteria or prolonged hospitalization. These specific situations could include the patient's physical condition, mental condition, socio-economical condition, and/or psycho-social condition. Therefore, the release of patients will be determined on an individual basis. In 2011, IAEA published their Interim General Safety Requirements Part 3, "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards" in cooperation with organizations such as the Nuclear Energy Association, the International Labor Organization, the World Health Organization, the Pan American Health Organization, the Food and Agricultural Organization, and the European Commission. This interim guidance states that patients may not be released from a medical radiation facility until the activity of radionuclides is such that doses that could be received by members of the public and family members would be in compliance with the requirements set by the relevant authorities. Similar to many organizations, the IAEA adopted and transitioned from an activity-based criteria to a dose-based criteria. It is not clear if other countries will update their practices to adopt the new IAEA criteria.

Staff is currently engaged in the early stages of a multi-year project in response to SRM-COMAMM-14-001/COMWDM-14-001, “Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance.” During this project, staff will engage many different interested individuals, organizations and other regulators. Staff will gather additional information about the implementation of patient release practices and the regulatory oversight by other nations’ programs to gain a more complete understanding of their practices, as part of this project. More dialogue with international organizations will be useful and informative as staff develops new patient release guidance, and considers the need to change the current regulations.

Enclosure:
Responses Gathered From Each Country

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Responses Gathered From Each Country

Country	Requirements	Standard Practice	Typical Activity Administered	Date of Latest Revision of Requirements
Australia	Patient dose rate must be <25 μSv /h (2500 μrem/h) at 1 m for release.		15 mCi (555 MBq) or 25 μSv /h (2500 μrem/h) for toxic thyroid, 50-200 mCi (1850-7400 MBq) (100 mCi (3700 MBq) average) for Ca thyroid.	Published in 2002. Currently under review.
Bangladesh (Unofficial Response)	Patient must have activity <1100 MBq (29.7 mCi) for release.			Guidelines revised in 2002.
Canada	Patients administered >1100 MBq (29.7 mCi) held for a few hours to ensure capsule is properly ingested. Released if they meet criteria for safe discharge (e.g., no children in home, separate bathrooms for patient and caregiver). Instructions provided at release.	Canadian Nuclear Safety Commission (CNSC) does not recommend release to hotels.	5-29 mCi (185-1073 MBq) (average 10-15 mCi (370-555 MBq)) for hyperthyroidism, 30-250 mCi (1110-9250 MBq) (average 100 mCi (3700 MBq)) for ablation.	Act came into effect in 2000. Multiple revisions since then. Radiation Protection regulations currently being considered for amendment
China	Patient have activity <400 MBq (10.8 mCi) for release.	Patients kept in separate clinic room until activity <400 MBq (10.8 mCi).	Varies according to patient needs.	Last revised in 2002.
France	Hospitalize patients when activity is >800 MBq (21.6 mCi). Doctor must provide written instructions to limit exposure to persons in contact with patient.	Hospitalize patients when activity is >800 MBq (21.6 mCi) for at least 48 hours until dose rate is <40 μSv /h (4000 μrem/h) at 1 m. Urine stored in special tanks for >80 days and until activity is <100 Bq/L (0.01	200 MBq-1 GBq (5.41-27.0 mCi) for hyperthyroidism, 1.1 GBq (29.7 mCi), 3.7 GBq (100 mCi) or 5.5 GBq (149 mCi) for thyroid cancer.	HERCA requirement approximate to actual practice.

Country	Requirements	Standard Practice	Typical Activity Administered	Date of Latest Revision of Requirements
		µCi/gal). Feces sent to the tank only to delay elimination towards sewage system.		
Germany	Hospitalize for at least 48 hours post treatment. Local dose rate must be <3.5 µSv/h (350 µrem/h) at 2 m or whole body activity must be <250 MBq (6.8 mCi) for release.	Hospitalize for at least 48 hours following thyroid carcinoma treatment. Ward equipped with separate waste water treatment installation.		Last revision in 2002.
Japan		Licensees are not allowed to isolate patients in hotels or other non-medical facilities. To reduce a patient's radiation to an acceptable level for release *(patients may be released when body residual radiation dose drops below 500 MBq (13.5 mCi) at 1m)*, they are isolated in a room designed for radiation therapy or a room where patients are administered radioactive medicines while in the hospital.	Medical doctors overseeing the patient must decide upon the activity to be provided. The guideline for thyroid cancer released by the Japanese Society of Nuclear Medicine and the Japanese Society of Nuclear Medicine in Oncology and Immunology notes the standard activities given to thyroid cancer patients is 3,700 -7,400 MBq.	The guideline was established on June 30, 1998, and revised on November 8, 2010. (2010's revised guideline, allowed thyroid cancer patients who were administered 1,110 MBq of I-131 for ablation therapy, after complete removal of their thyroid due to differentiated cancer and without distant metastasis, to go home directly.)
Lithuania	Patient must have activity <400 MBq (10.8 mCi) for release.	Hospitalize for 3 days.	200-300 MBq (5.4-8.1 mCi) for hyperthyroidism, 1.6-3.2 GBq (43-86 mCi) for thyroid cancer.	Reviewed in 2013.

Country	Requirements	Standard Practice	Typical Activity Administered	Date of Latest Revision of Requirements
Malaysia	Patient must have activity <1100 MBq (29.7 mCi) for release.	Patients administered <1100 MBq (29.7 mCi) are released. No special transportation arrangements are made. Patients administered >1100 MBq (29.7 mCi) kept in isolation ward until activity below legal limit (i.e., under article 9(5)).	10-20 mCi (370-740 MBq) for hyperthyroidism, 80-150 mCi (2960-5550 MBq) for thyroid cancer.	Current regulation came into effect in 2010. No plans for revision.
New Zealand	Patients administered >800 MBq (21.6 mCi) are hospitalized (normally only thyroid ablations). No visits from children or pregnant women. Maximum ambient dose rate must be <0.05 mGy/h (5 mrad/h) at 1 m for release.	Patients treated with >800 MBq (21.6 mCi) kept in an isolated room with its own bathroom. Cannot travel by public transport until activity <400 MBq (10.8 mCi). Cannot return to work until activity <250 MBq (6.8 mCi). Cannot be in close contact with children until activity <50 MBq (1.4 mCi).		
Philippines	Total effective dose must be <3 mSv (300 mrem) for release. Required written instructions to patient or legal guardian. Hospitalized patients must have a private sanitation facility.		3-30 mCi (111-1110 MBq) for hyperthyroid, 50-250 mCi (185-9250 MBq) for thyroid cancer.	"Licenses for Medical Use of Unsealed Radioactive Materials" published in Volume 110, No. 12 of the Official Gazette on March 24, 2014.
Poland	Patient must have activity <800 MBq (21.6 mCi) for release.	Pregnant women after 8 weeks of gestation cannot be administered I-131. Single ambulatory treatment of open sources of I-131 must be <8 MBq (0.216 mCi). Written instructions are provided.		Last revision in 2011.

Country	Requirements	Standard Practice	Typical Activity Administered	Date of Latest Revision of Requirements
Portugal	Dose rate at 1 m cannot surpass derived dose limit for members of the general public.	Patients administered 140-500 MBq (3.8-13.5 mCi) are released immediately. Hospitalized patients (treatments with 5000-11100 MBq (135-300 mCi) must be kept in an isolated hospital room with its own bathroom. All excreta are channeled to separate decay tanks until they can be discharged into the environment.	140-500 MBq (3.8-13.5 mCi) for typical procedures, 5000-11100 MBq (135-300 mCi) for special procedures.	Current regulation was published in 2002 Expected to be reviewed and updated before 2018.
South Africa	Patient dose rate must be <2.5 μSv/h (2500 μrem/h) for release. Isolated bathroom for exclusive use. Children treated with MIBG must have activity <550 MBq (15 mCi) for release.	Isolated hospital room. Excreta are disposed into sewage system as non-radiation waste and does not need to be stored for any time.	Varies according to patient needs.	Last revision in 1993.
Spain	Patient must have activity <800 MBq (21.6 mCi) or have a dose rate <40 mSv/h (4000 mrem/h) for release.	Doctor must provide written and verbal instructions. Patients are released upon comprehension of instructions.		Currently under revision to unify the international basic recommendations (ie IAEA, HERCA) for high radiation treatments.
Taiwan	No written rules but adhere to principle of 10 CFR 35.75.	Medical society decides if patients administered >1100 MBq (29.7 mCi) will be hospitalized. Common practice to stay in hospital for 3 days. Dose rate must be <70 μSv/h (7000 μrem/h) at 1 m for release. Patients return to hospital for whole body scanning and follow-up checking.		Potential revision in 2015.

Country	Requirements	Standard Practice	Typical Activity Administered	Date of Latest Revision of Requirements
UK	Patients administered <800 MBq (21.6 mCi) released same day with written. If patient administered >800 MBq (21.6 mCi), patient stays in dedicated therapy suite with shielded room.	No known hospitals that would discharge patient to a hotel. However, if patient is discharged to another hospital or nursing home, the treating hospital has to provide advice on radiation safety precautions (as for hotels).	400-600 MBq (10.8-16.2 mCi) for hyperthyroidism, 1.1 GBq (29.7 mCi) for patients with pT1-2, 3.7-5.5 GBq (100-148.6 mCi) for patient with known residual local disease following radiation remnant ablation or distant metastases.	2000 with revisions expected in 2018.