

Summary of Staff Gap Analysis (Task 1)

As instructed in SRM-COMGBJ-11-0003, "Data Collection Regarding Patient Release," a gap analysis was performed by reviewing available articles in scientific and medical journals, as well as national and international radiation protection documents (see list of references). The available literature reviewed revealed that while there are a number of different isotopes used for medical purposes today, only a few were studied. Although this may appear to be a gap in the data this is not the case, because the isotopes studied are the ones that result in the delivery of the highest radiation doses to members of the public. Almost all of the published literature reviewed addressed doses from Iodine-131 (I-131) hyperthyroid and thyroid cancer patients and focused on releases to primary residences (e.g., houses, apartments).

The staff searched for articles on doses (internal and external) from exposure to patients that were administered medical isotopes either on an outpatient or inpatient basis (Ref. 1-22). Many articles focused on the diagnostic/therapeutic quantities of medical isotopes administered and how it impacted patient release (Ref. 1-15). In addition to the United States, patient release studies were performed in India, Pakistan, Japan, England, Belgium, and the Middle East. (Ref. 4, 5, 9-14). Patient release protocols in these countries were analyzed based on release criteria, including radiopharmaceutical limits and quantity allowed for release. Generally, in most of these foreign countries, the limits established for the total activity of radiopharmaceuticals administered to patients are lower than the limits for activity of radiopharmaceuticals administered to patients in the United States. Therefore, when considering doses from released patients to members of the public in these countries, it follows that all of these doses were below the regulatory dose limit set by the U.S. Nuclear Regulatory Commission (NRC) for release of patients, with the exception of doses to some members of the public who willingly chose to care for a patient at close proximity, and others who didn't follow provided guidance. This demonstrates the importance of socioeconomic and cultural considerations when making patient release decisions (Ref. 4, 5, 9-14).

There were articles addressing doses and potential doses from patients while traveling by different means of transportation (e.g., air, bus, train, private vehicle or other public transport) after their release, addressing the patient's proximity to others (including family, small children, radiation workers, hospital staff, etc.), and doses to accompanying individuals that might be present at any given moment and exposed to the released patient. No gap was identified with regard to this issue. One article assessed the dose from the care of the indigent and/or incontinent radioactive patients (Ref. 1).

The available published data was closely scrutinized for information on doses imparted to others after release of the patient to a primary residence and alternative locations (such as a hotel, motel, nursing homes, dormitory, etc.), and the release instructions provided to the patient. A number of studies concluded that I-131 outpatient therapy, with the patient released to a primary residence can be performed safely (Ref. 3, 5, 7-11). No articles reviewed included information on measured or calculated doses from patients released to alternative locations such as a hotel, motel, nursing homes, dormitory, etc. This was identified as a gap in the data.

Existing data supports that radiation doses delivered to other individuals can be safely controlled by current patient release regulations (10 CFR 35.75) (Ref. 20). Studies that monitored released patients administered < 30 mCi I-131 have reported that the delivered radiation doses to other individuals are below 5 mSv, even in cases where the released patient has used public transport (train and bus) as a means of returning to his primary residence (Ref. 13). This activity amount (< 30 mCi of I-131) is significantly lower than the activity in released patients in the United States.

National and International scientific radiation protection documents summarized findings from other studies. These findings were incorporated into their recommendations on patient release that appear to be consistent, in principle and practice, with NRC patient release regulations and guidance (Ref. 23). They focused on whether families of outpatients receiving radioiodine could comply with statutory dose limits and constraints (Ref. 11) and indicate that with proper instructions and recommendations, this could be achieved. Further studies indicate that nurses caring for an indigent patient and medical personnel that may handle a radioactive corpse, with appropriate radiation protection guidelines and recommendations, can be reassured that their doses in these specific circumstances are very low (Ref. 1).

Clinical data suggest that hyperthyroid and thyroid cancer patients can continue to be treated with radioiodine on an out-patient basis, if given appropriate radiation protection advice (Ref. 7). However, particular consideration needs to be given to children aged 3 years or younger, if they may be exposed to the released patient or patient fluids (Ref. 23). While various studies highlighted that the internal radiation doses delivered primarily from radioiodine contamination were very low after release to a residence, the amount of I-131 administered in these cases was significantly lower than that generally administered in most I-131 clinical administrations in the United States (Ref. 15-17).

No articles reviewed included information on the measurement of internal doses delivered to members of the public primarily from inhalation and/or ingestion of radioactive contamination (perspiration, body fluids [saliva, blood, sweat, urine, etc.]) when considering the increased activities administered in today's patient release practices. This was identified as a gap in the data.

The NRC staff is in agreement with the Advisory Committee on the Medical Uses of Isotopes' (ACMUI's) "Draft Patient Release Subcommittee Report" conclusion that the current NRC release criteria appropriately balance public safety with patient access to medical treatment. However, the NRC's position as established in a recently issued Regulatory Issue Summary (RIS) 2011-01, "NRC Policy on Release of Iodine-131 Therapy Patients under 10 CFR 35.75 to Locations Other than Private Residences" is that although 10 CFR 35.75 does not expressly prohibit the release of a radioactive patient to a location other than a private residence, the NRC strongly discourages this practice because it can result in radiation exposures to members of the public for which the licensee may not be able to fully assess compliance with 10 CFR 35.75(a) and may result in doses which are not as low as reasonably achievable (ALARA).

In summary, the gap analysis findings indicate that there are gaps in the available existing empirical data for release of patients to locations other than their primary residences, and particularly for exposure scenarios at nursing homes and exposure scenarios to hotel staff and guests. Gaps also were identified in the analysis of internal doses delivered to members of the public primarily from radioiodine contamination released from the patient's body, when considering today's patient radioiodine administration and release protocols.

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